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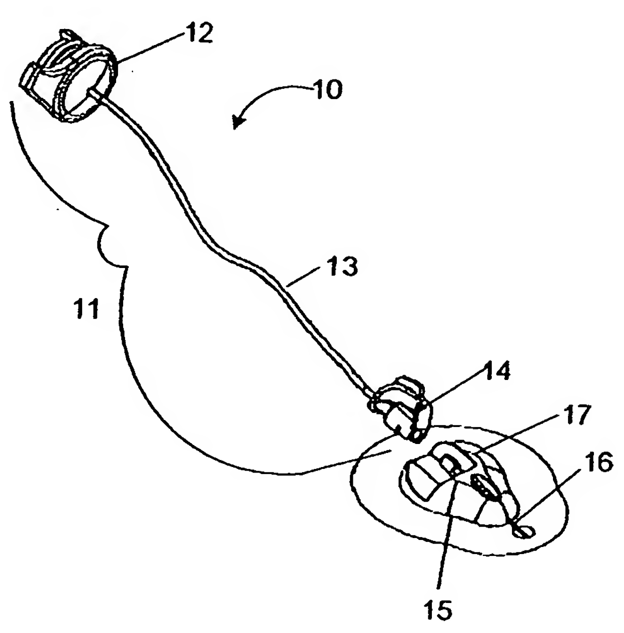
(54) Title: INFUSION SET FOR A FLUID PUMP



(57) Abstract: A medical device for delivery of a fluid to a patient from a line terminating in a tubing needle. The medical device includes a cannula assembly for coupling the fluid into a cannula that is inserted into the patient. The cannula assembly has a first locking element disposed in a fixed position with respect to the cannula. Coupling the line to the cannula assembly is an infusion flap. The infusion flap includes a second locking element for engaging the first locking element of the cannula assembly and a lift tab for disconnecting the infusion flap from the cannula assembly. Coupling of the first and second locking elements requires initial mating of the infusion flap with respect to the cannula assembly.

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Infusion Set for a Fluid Pump

Technical Field and Background Art

The present invention relates to a system and method for delivery of a fluid to a patient, and more particularly, to an infusion set for a fluid pump that may be used, for example, to deliver insulin to a patient.

Currently, there are two primary methods of treating diabetes. One method involves taking multiple injections of long acting insulin on a daily basis. The second method is by continuous delivery of short acting insulin to more closely emulate the human pancreas. This may be accomplished using a syringe pump.

A syringe pump typically includes four major components. These components are a microprocessor controlled syringe pump, an insulin filled syringe, a hub and tubing set, and a cannula.

A syringe pump is often worn in a carrying case on a patient's belt, in a manner similar to a pager, or in more discrete locations such as a pocket or a brassiere. The syringe is mounted in the syringe pump and may hold enough insulin for three days. The hub serves as an interface between the syringe and a tubing set. At the end of a tubing set is a cannula typically made of either steel or Teflon. The cannula may advantageously be carried in a cannula assembly. The cannula assembly typically attaches to the patient by adhesive and is placed near the abdomen around and to the side of the navel. The cannula is inserted in fatty tissue and the insulin is injected subcutaneously.

A patient may perform activities that do not permit or are hindered by the presence of a pump, for example, when a patient wishes to take a shower or participate in certain athletic activities. Removing each of the components, including the cannula, would require a needle stick upon reconnecting the system to a patient. Since a needle stick is undesirable every time one wishes to take a shower or participate in sports, state of the art tubing sets disconnect at or near the cannula assembly, with the tubing capped to prevent contamination. Disconnecting and reconnecting the tubing set is sometimes difficult.

Cannulas with steel subcutaneous needles have been used with syringe pumps for decades. Steel needles, however, can cause irritation and discomfort. Soft cannulas, which may be made of Teflon, for example, help prevent this discomfort and are generally known in the art. The soft cannula requires the use of a steel insertion needle to penetrate skin and/or other tissue. When inserting the needle, the needle penetrates a first self-sealing septum in the cannula housing. The needle is then pushed through the soft cannula until it extends through the cannula's outer tip. After insertion of the needle into the skin, the steel needle is removed and the first septum seals the opening where the insertion needle entered. The tubing set may then be connected to the cannula by inserting a tubing needle at the end of the tubing set into a second septum in the cannula housing.

After removing the insertion needle, the first septum may be susceptible to leakage. This leakage may become more prevalent under pressure, such as when the cannula has an occlusion. Normally during an occlusion, the pressure will reach a threshold and trigger an alarm on the pump. However, if the first septum leaks, the pressure may never reach the threshold, and the pump may continue to deliver insulin. As a result, the insulin will continue to leak out of the first septum, the alarm will never trigger, and the user unknowingly does not receive the drug for an indefinite period of time.

Summary of the Invention

In a first embodiment of the invention there is provided a medical device for delivery of a fluid to a patient from a line terminating in a tubing needle. The medical device includes a cannula assembly for coupling the fluid into a cannula that is inserted into the patient. The cannula assembly has a first locking element disposed in a fixed position with respect to the cannula. Coupling the line to the cannula assembly is an infusion flap. The infusion flap includes a second locking element for engaging the first locking element of the cannula assembly and a lift tab for disconnecting the infusion flap from the cannula assembly. Coupling of the first and second locking elements requires initial mating of the infusion flap and cannula assembly, followed by locking through rotation of the infusion flap with respect to the cannula assembly.

In a related embodiment, the cannula assembly may include a septum housing defining a core coupled to the cannula. The septum housing includes a first septum positioned within the core at a first position, such that when the infusion flap and the

cannula assembly are locked, the tubing needle penetrates the first septum so as to permit fluid communication between the line and the cannula. The septum housing may also include a second septum positioned within the core at a second position, such that an insertion needle can be introduced through the second septum into the cannula.

In another related embodiment of the invention, the cannula assembly further includes a flexible tube in fluid communication with both the cannula and a septum. When the flexible tube is in a first position, an insertion needle can be introduced through the septum into the cannula, and when the flexible tube is in a second position, a tubing needle inserted through the septum permits fluid communication between the line and the cannula.

In yet another related embodiment of the invention, the device further includes an insertion flap. The insertion flap includes an insertion needle for inserting through the septum and terminating with a sharp distal end disposed slightly beyond a distal end of the cannula. The insertion flap has an interface for coupling to an auto-insertion device.

In other related embodiments, the first locking element may be a locking lug and the second locking element is a lug receptacle, or vice versa. The cannula assembly may include a soft overmolded body.

In accordance with another embodiment of the invention, a medical device for delivery of a fluid to a patient from a line terminating in a tubing needle is presented that includes a a cannula for insertion into the patient. A flexible tube is in fluid communication with both the cannula and a septum. When the flexible tube is in a first position, an insertion needle can be introduced through the septum into the cannula, and when the flexible tube is in a second position, a tubing needle inserted through the septum permits fluid communication between the line and the cannula.

In accordance with related embodiments of the invention, the device further includes an infusion flap that includes the tubing needle and a cannula assembly that includes the cannula. When the infusion flap and cannula assembly are mated, the tubing needle passes through the septum permitting fluid communication between the line and the cannula. The device may further include a locking mechanism for securing the infusion flap to the cannula assembly. The locking mechanism may include a locking tang on the infusion flap, the locking tang inserted into a tang receptacle on the cannula assembly. As another example, the locking mechanism may include a first locking element disposed on a septum housing containing the septum, and a second locking element disposed on the infusion flap. Coupling the first and second locking elements

may require initial mating of the infusion flap and cannula assembly followed by locking through rotation of the infusion flap with respect to the cannula assembly. In various embodiments, the first locking element is a locking lug and the second locking element is a lug receptacle, or vice versa. In various embodiments, the septum housing can be rotated to a mating position that allows the infusion flap and the septum housing to be mated together and the infusion flap rotated with respect to the cannula assembly to lock the infusion flap onto the septum housing. The septum housing can then be rotated to a stable position that prevents rotation of the infusion flap.

In accordance with another embodiment of the invention, a method for delivering a fluid to a patient from a line terminating in a tubing needle is presented. The method includes inserting an insertion needle through a septum and a cannula, the septum and the cannula having a relative orientation. The cannula is inserted into tissue of a patient. After withdrawing the insertion needle from the cannula and the septum, a tubing needle is inserted through the septum. The relative orientation between the septum and the cannula is varied and the fluid is delivered through the line and the cannula.

In accordance with still another embodiment of the invention, a tubing set for coupling a fluid delivery device containing a fluid source into fluid communication with a cannula assembly is presented. The tubing set includes a length of tubing having a first end and a second end. A hub is coupled to the first end for connecting to the fluid delivery device. The hub includes a controller which allows the fluid delivery device to transition from a first configuration to a second configuration. An infusion flap is coupled to the second end for connecting to the cannula assembly.

In another related embodiment of the invention, the first configuration of the fluid delivery device may be a reservoir load position and the second configuration may be an operate position. The controller may be capable of allowing the fluid delivery device to transition from the second configuration to the first configuration. The controller may include a flange that interfaces with the fluid delivery device. In other embodiments, the controller may include an electronic circuit to the fluid delivery device, or generating one of an optical signal and magnetic field. The hub may include a luer connector for mating with the fluid delivery device.

In another related embodiment of the invention, the fluid delivery device may be an infusion pump having a reservoir with variable volume and a drive assembly. The drive assembly includes a barrel having a clearance hole in a barrel end, the barrel characterized by a longitudinal barrel axis of rotation. The drive assembly further

includes a plunger rod inserted through the clearance hole, and a rotating drive screw with external threads. The external threads removably engage with threads on the plunger rod by rotating the barrel about the barrel axis. The external threads are engaged with the threads on the plunger rod when in the first configuration and the external threads are disengaged with the threads on the plunger rod when in the second configuration. The controller is capable of allowing the barrel to rotate so as to bring the rod threads in and out of mechanical engagement with the drive screw threads. The controller may include a flange for dislodging a locking tab on the barrel, allowing the barrel to rotate.

In accordance with still another embodiment of the invention, a conduit for coupling to a fluid delivery device is presented. The conduit includes a length of tubing having a first end. A hub is coupled to the first end for connecting to the fluid delivery device. The hub includes a controller which allows the fluid delivery device to transition from a first configuration to a second configuration.

In related embodiments of the invention, the first configuration may be a reservoir load position and the second configuration may be an operate position. The hub may include a luer connector for mating with the fluid delivery device. The controller may include a flange that interfaces with the fluid delivery device. The controller may include an electronic circuit to the fluid delivery device, or generating one of an optical signal and magnetic field.

In still yet another embodiment of the invention, a method of providing flow of a fluid from a fluid delivery device to a porous medium is presented. The method includes coupling a hub, permanently affixed to a tube set, to the fluid delivery device. Configuration of the fluid delivery device is controlled via the hub. The tube set is coupled to the porous medium so as to allow fluid to flow from the fluid delivery device to the porous medium.

In related embodiments of the invention, controlling the configuration of the fluid delivery device may include allowing the pump to move from a first configuration to a second configuration. The first configuration of the fluid delivery device may be a load position and the second configuration may be an operate position. Controlling the configuration of the fluid delivery device may include moving a flange on the hub or generating one of a magnetic field and an optical signal. The fluid delivery device may be an infusion pump.

Brief Description of the Drawings

The foregoing features of the invention will be more readily understood by reference to the following detailed description, taken with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of an infusion set 10 for delivery of a fluid to a patient, in accordance with one embodiment of the present invention;

Fig. 2 is a further breakdown of the infusion set shown in Fig. 1, in accordance with one embodiment of the present invention;

Fig. 3 is a cross-sectional view of a cannula assembly with an insertion flap attached (and locked), in accordance with one embodiment of the present invention;

Fig. 4 is a cross-sectional view of an infusion flap mated (and locked) to a cannula assembly, in accordance with one embodiment of the present invention;

Fig. 5 is a side view of the embodiment of Fig. 4 with the infusion flap in position for mating with the cannula assembly;

Fig. 6 is a perspective view of the embodiment of Fig. 4 with the infusion flap mated to the cannula assembly;

Fig. 7 is a top view of the embodiment of Fig. 4 with the tubing set locked to the cannula assembly;

Fig. 8 is a side view of the embodiment of Fig. 4 with the tubing set locked to the cannula assembly;

Fig. 9 is a cross-sectional view of an infusion flap mated (and locked) to a cannula assembly that includes a first septum and a second septum contained with a septum housing, in accordance with one embodiment of the present invention;

Fig. 10 is a top view of the embodiment of Fig. 9 with the infusion flap in position for mating with the cannula assembly;

Fig. 11 is a side view of the embodiment of Fig. 9 with the infusion flap in position for mating with the cannula assembly;

Fig. 12 is a perspective view of the embodiment of Fig. 9 with the infusion flap mated to the cannula assembly;

Fig. 13 is a cross-sectional view of an infusion flap mated (and latched) to a cannula assembly, wherein the cannula assembly includes a single septum located in a rotatable septum housing, in accordance with one embodiment of the present invention;

Fig. 14 is a perspective view of the embodiment of Fig. 13 with the infusion flap in position for mating with a cannula assembly;

Fig. 15 is a side view of the embodiment of Fig. 13 with the infusion flap in position for mating with the cannula assembly;

Fig. 16 is a perspective view of the embodiment of Fig. 13 with the infusion flap mated and latched onto the cannula assembly;

Fig. 17 is a side view of the embodiment of Fig. 13 with the infusion flap mated and latched onto the cannula assembly;

Fig. 18 is a perspective view of embodiment of Fig. 13, with the infusion flap latched to the septum housing and the septum housing rotated 90 degrees;

Fig. 19 is a cross-sectional view of an infusion flap that includes a single septum located in a rotatable septum housing, in accordance with one embodiment of the invention;

Fig. 20 is a perspective view of the embodiment of Fig. 19 with the infusion flap in position for mating with the cannula assembly;

Fig. 21 is a top view of the embodiment of Fig. 19 with the infusion flap in position for mating with the cannula assembly;

Fig, 22 is a side view of the embodiment of Fig. 19 with the infusion flap in position for mating with the cannula assembly;

Fig. 23 is a perspective view of the embodiment of Fig. 19 with the infusion flap mated with the cannula assembly 1902;

Fig. 24 is a side view of the embodiment of Fig. 19 with the infusion flap mated with the cannula assembly 1902;

Fig. 25 is a perspective view of the embodiment of Fig. 19 with the locking lug engaged with the lug receptacle by rotating the infusion flap 25;

Fig. 26 is a perspective view of the embodiment of Fig. 19 after the locking lug is engaged with the lug receptacle and the septum housing 1904 is rotated;

Fig. 27 is a top-level view of a hub and infusion pump, in accordance with one embodiment of the present invention;

Fig. 28 is an exploded view of a drive mechanism for the infusion pump of Fig. 27;

Fig. 29 shows an embodiment of a pump barrel locking mechanism of Fig. 27;

Fig. 30 is an exploded view of the pump barrel locking mechanism of Fig. 27;

Fig. 31 shows the relation of the drive screw to the plunger rod for the infusion pump of Fig. 27 when in a loading position;

Fig. 32 shows the relation of the drive screw to the plunger rod for the infusion pump of Fig. 27 when in an engaged position;

Fig. 33 shows a connection between the locking hub and the reservoir in accordance with one embodiment of the present invention;

Fig. 34 shows another connection between the locking hub and the reservoir in accordance with one embodiment of the present invention;

Fig. 35 shows an adapter for using a small diameter reservoir with the pump assembly in accordance with one embodiment of the present invention;

Fig. 36 is an on-axis view of the adapter in Fig. 35 when the pump is in a loading position; and

Fig. 37 is an on-axis view of the adapter in Fig. 35 when the pump is in an engaged position.

Detailed Description of Specific Embodiments

Fig. 1 is an overall view of an infusion set 10, in accordance with one embodiment of the invention, for delivery of a fluid to a patient. It may also be used to deliver fluid from a fluid delivery device to a porous medium. In the description, an infusion pump will serve as an example of a fluid delivery device and a human tissue will serve as an example of a porous medium. Fluid may be, for example, a drug, such as insulin. Like numbers in successive figures refer to the same or similar items.

The infusion set 10 includes a tubing set 11. The tubing set 11 includes tubing 13 that is attached at one end to a hub 12. The hub 12 serves as an interface between the tubing 13 and a pump assembly (not shown). Attached to the other end of the tubing set 11 is an infusion flap 14 that interfaces with a cannula assembly 15.

The cannula assembly 15 includes a cannula body 17. Attached to the cannula body 17 is a cannula 16, for subcutaneous insertion into the patient. The cannula 16 may be made of steel or alternatively, a soft and/or flexible material to help prevent patient discomfort, such as Teflon or other plastic. The cannula 16 may protrude from the bottom or side of the cannula body 17 at various angles. For example, without limitation, the cannula 16 may protrude from the front edge of the cannula body 17 at a shallow angle of 15-30 degrees. As another example, the cannula 16 may form a 90 degree angle with the bottom of the cannula body 17. Further detail of the cannula assembly 15 is provided in subsequent drawings including Fig. 2.

Within the cannula body 17 is a passageway adapted to receive the proximal or upstream end of the cannula 16. The passageway includes at least one self-sealing septum that can be penetrated, for example, by an infusion or insertion needle.

Fig. 2 is a further breakdown of parts in the infusion set shown in Fig. 1. The cannula assembly may be fabricated, in accordance with one embodiment of the invention, by inserting the cannula 16 through a hole in a cannula locking ring 21. The cannula locking ring 21 is then attached to a core insert 22 by a snap fit mechanism, ultrasonic welding, or other means known in the art. The proximal end of the cannula 16 is flared, such that it is captured and held in place between the core insert 22 and the locking ring 21. Both the cannula locking ring 21 and core insert 22 may be made of plastic or other suitable material.

The core insert 22 defines a passageway having a first end and a second end. The first end receives the proximal end of the cannula 16, as described above. The second end of the core insert 22 acts as septum housing 23. A self-sealing septum 24 is inserted into the open end of the septum housing 23, which is then ultrasonically flared to capture the septum 24 inside the core insert 22. The core insert 22 and locking ring 21 are then overmolded to form a soft body 17 for user comfort.

The body 17 of the cannula assembly is typically a compact and low profile component. When seen from the top, the cannula body 17 may be, for example, circular, elliptical or triangular in shape and/or advantageously elongated for easy patient handling. All or a portion 201 of the body 17 may be made clear or transparent to facilitate viewing of the core insert 22 and/or infusion site.

The cannula 16 may be inserted subcutaneously with the aid of an insertion flap 25. The insertion flap 25 includes an insertion needle 26, typically made of steel, that assists the cannula 16 in penetrating the skin. After inserting the cannula 16, the insertion flap 25 is removed, and the infusion flap 14 is removably attached to the cannula assembly 15 for delivery of fluid to the patient.

In accordance with one embodiment of the invention, Fig. 3 shows a cross-sectional view of the cannula assembly 15 with the insertion flap 25 attached. The insertion flap 25 supports a proximal end of the insertion needle 26 which protrudes from the flap 25 and terminates in a sharp distal end. When the insertion flap 25 is not in use and is removed from the cannula assembly 15, the sharp end of the insertion needle 26 may be covered by a needle guard 202 (shown in fig. 2), which prevents accidental contact with the needle 26.

The proximal end of the insertion needle 26 is seated within a cylindrical shaped open ended (female) connector 31 that slides onto and mates with the male septum housing 23 of the cannula assembly 15. The distal end of the insertion needle 26 is inserted through the self-sealing septum 24, through the core insert 22, and into the cannula 16. When the insertion flap 25 and septum housing 23 are fully mated, the sharp tip of the insertion needle 26 may extend slightly beyond the distal end tip of the cannula 16. The insertion flap may interface with an auto-insertion device (not shown) that can be used, for example, by a patient lacking the dexterity or strength to subcutaneously insert the cannula 16 by him or her self. To interface with the auto-insertion device, the insertion flap 25 may include, for example, a flat top with a pair of wings 205 and 206 and mounting holes 203 and 204 for attaching the auto-insertion device (see Fig. 2). When manually inserting the cannula 16, the patient grasps the attached insertion flap 25 and/or cannula body 17 and pushes the cannula 16, with the insertion needle 26 inserted, into the infusion site. The infusion site may be prepped prior to insertion of the cannula 16 with a sterilizing fluid or by placement of a mounting patch onto the patient's skin, as known in the art. After the cannula 16 has been inserted into the patient, the insertion flap 25 and needle 26 is withdrawn from the cannula assembly 15. The cannula assembly 15 can then be secured to the patient by peeling a cover off an adhesive strip coupled to the bottom of the cannula body 17, and pressing the adhesive 281 against the patient's skin or mounting patch.

Referring back to figs. 1 and 2, upon securing the cannula assembly 15 to the patient, the infusion flap 14 is attached to the cannula assembly 15 permitting fluid communication between the tubing set 11 and the cannula 16. The infusion flap 14 may attach to the top or one of sides of the cannula assembly 15. In accordance with one embodiment of the invention, Fig. 4 is a cross-sectional view of the infusion flap 14 mated (and locked) to the cannula assembly 15. The infusion flap 14 includes an infusion needle 42 attached to the inside of the tubing 13, by, for example, a suitable adhesive. In various embodiments, the tubing may be microbore tubing. The proximal end of the infusion needle 42 is seated within a generally cylindrically shaped, open ended, female connector 45 on the infusion flap 14 that slides onto and mates with the male septum housing 23 of the cannula assembly 15. The sharp, distal end of the infusion needle 42 typically does not extend beyond the open end of the female connector 45, preventing inadvertent needle sticks and/or damage to the needle. When the infusion flap 14 is mated to the cannula assembly 15, the infusion needle penetrates the septum 24, allowing

fluid in the tubing 13 to flow through the cannula 16. The length of the infusion needle 42 is such that it does not protrude into, and damage the cannula 16.

So as to prevent inadvertent separation of the infusion flap 14 and the cannula assembly 15, a locking mechanism may be provided. The locking mechanism may include, without limitation, a locking receptacle 43 on the female connector 45 of the infusion flap 14 that engages a locking lug 44 on the core insert 22 of the cannula assembly. The locking lug 44 may be disposed on the septum housing 23, for example. Fig. 5 is a side view showing the infusion flap 14 in position for mating with the cannula assembly 15. To slide the male septum housing 23 into the female connector 45, an opening slot 51 of the receptacle 43 is aligned with the locking lug 44. When fully inserted, the base wall of the female connector 45 may abut the distal end of the male septum housing 23, and/or the distal end of the infusion flap 14 may make contact with the body of the cannula assembly 15, such that the infusion needle pierces the septum contained within the septum housing.

Fig. 6 is a detailed perspective view showing the infusion flap 14 when mated to the cannula assembly 15. To lock the infusion flap 14 onto the cannula assembly 15, the locking lug 44 (shown in Fig. 4) is engaged with the lug receptacle 43 by rotating the infusion flap 14 clockwise. The locking lug 44 (shown in Fig. 4) prevents the infusion flap 14 from disconnecting with the cannula assembly 15 when a longitudinal force is applied, such as when the tubing 13 is pulled on. In various embodiments, the infusion flap 14 may also include a snap fit mechanism to prevent the infusion flap 14 from inadvertently rotating open. The snap fit mechanism may include, without limitation, a detent 62 that, when the infusion flap 14 is rotated clockwise, fits into a notch 63 in the cannula body 17.

Figs. 7 and 8 show a top view and side view of the tubing set 11 locked to the cannula assembly. The infusion flap 14 can be easily removed from the cannula assembly 15 by lifting up on a lift tab 71 on the infusion flap 14 and rotating the infusion flap 14 counter-clockwise so as to align the slot 51 (shown in Fig. 4) with the locking lug 44 (shown in Fig. 4). The infusion flap 14 is then pulled apart from the cannula assembly 15 and the septum 24 (shown in Fig. 4) self-seals.

In accordance with another embodiment of the invention, Fig. 9 shows a cross-sectional view of an infusion flap 97 attached to a cannula assembly 91 that includes a first septum 92 and a second septum 93 contained with a septum housing 94. The septum housing 94 defines a passageway that is coupled to a cannula 95. The first septum 92 is

advantageously located for penetration by an insertion needle 96, while the second septum is positioned for penetration by an infusion needle 99. To subcutaneously insert the cannula 95, the insertion needle 96 is inserted through the first septum 92 and into the cannula 95. After cannula 95 insertion, the insertion needle 96 is removed and the first septum 92 self-seals to prevent fluid leakage. The cannula assembly 91 attaches to the user's body or mounting patch with an adhesive.

As in previous embodiments, tubing 98 is coupled at a first end to the infusion flap 97, and to a hub (not shown) that interfaces with a pump assembly at a second end. An infusion needle 99 is attached to the inside of the tubing 98 at the first end and is seated within a generally cylindrically shaped, open ended, female connector 901 on the infusion flap 97. When the infusion flap 97 is mated to the cannula assembly 91, the connector 901 slides onto and mates with the male septum housing 94, such that the infusion needle 99 pierces the second septum 93 allowing fluid in the tubing 98 to flow to the cannula 95.

Figs. 10 and 11 are a top view and a side view of the infusion flap 97 in position for mating with the cannula assembly 91. The insertion needle 96 has been removed. To prevent inadvertent separation of the infusion flap 97 and the cannula assembly 91, a locking mechanism for securing the infusion flap 97 to the cannula assembly 91 may be provided. For example, the cannula assembly 91 may include a lug receptacle 1001 (see Fig. 10) that engages with a locking lug 1101 (see Fig. 11) on the infusion flap 97. To lock the infusion flap 97 to the cannula assembly 91, the locking lug is engaged with the lug receptacle 1001 by rotating the infusion flap clockwise. Engagement in this fashion prevents disconnection of the tubing when pulled on. Fig. 12 shows the infusion flap 97 mated and locked onto the cannula assembly 91.

To remove the infusion flap 97 from the cannula assembly 91, one lifts up on a lift tab 1201 and rotates the infusion flap 97 counter-clockwise. The infusion flap 97 is then pulled apart from the cannula assembly 91 and the second septum 93 (see Fig. 9) self-heals.

In accordance with another embodiment of the invention, Fig. 13 is a cross-sectional view of an infusion flap 1301 attached to a cannula assembly 1302, wherein the cannula assembly 1302 includes a single septum 1303 located in a rotatable septum housing 1304. A single septum 1303 and rotatable septum housing 1304 advantageously prevents leakage problems inherent in dual septum designs, while still permitting the

septum housing 1304 to be positioned, for example, vertically for insertion of an insertion needle 1305, or horizontally after mating with the infusion flap 1301.

The septum housing 1304 is rotatably attached to the cannula assembly by, for example, a pivot or hinge mechanism. Attached to the septum housing 1304 and/or septum 1303 is a first end of a flexible tube 1306, which is further attached at a second end to a proximal end of a cannula 1307 mounted within the cannula assembly 1302. The flexible tubing 1306 may be attached to the septum housing 1304 and/or cannula assembly 1302 using, without limitation, a suitable adhesive.

Tubing 1308 is coupled at a first end to the infusion flap 1301, and to a hub (not shown) that interfaces with a pump assembly at a second end. An infusion needle 1309 is attached to the inside of the tubing 1308 at the first end and is seated within an open ended, female connector 1310 on the infusion flap 1301. The connector 1310 and male septum housing 1304 may be of variable shape, such as, for example, a cylindrical, rectangular, or square shape. When the infusion flap 1301 is mated to the cannula assembly 1302, the connector 1310 slides onto and mates with the male septum housing 1304, such that the infusion needle 1309 pierces the septum 1303 allowing fluid in the tubing 1308 to flow to the cannula 1307. In various embodiments, the infusion needle 1305 is slightly larger than the insertion needle 1305, so as to seal the hole previously created by the insertion needle 1305.

The infusion flap 1301 is easily connected and disconnected to the cannula assembly 1302. Figs. 14 and 15 show a perspective view and a side view, respectively, of the infusion flap 1301 in position for mating with the cannula assembly 1302. The septum housing 1304 has been rotated such that it is perpendicular to the longitudinal axis of the cannula assembly 1302, so as to allow for insertion of the infusion flap 1301. The insertion needle 1305 has been removed. To prevent inadvertent separation of the infusion flap 1301 and the cannula assembly 1302, a locking mechanism may be provided. The locking mechanism may include, for example, locking tangs 1401 and 1402 on the infusion flap 1301 which engage with tang receptacles 1403 and 1404 located on the cannula assembly 1302 when the infusion flap 1301 is pushed onto the cannula assembly 1302. Figs. 16 and 17 show a perspective view and a side view, respectively, of the infusion flap 1301 mated and latched onto the cannula assembly 1302. At this point, the infusion needle 1309 penetrates the septum 1303 in the septum housing 1304 (see Fig. 13). Upon being mated and latched onto the cannula assembly 1302, the infusion flap 1301 and septum housing 1304 may be rotated 90 degrees, such

that the infusion flap lays flat against the cannula assembly 1302, as shown in Fig. 18. A detent (not shown) may latch the infusion flap 1301 to the cannula assembly 1302 with a snap action. The flexible tube 1306 bends as the septum housing 1304 rotates, providing a leak tight fluid path between the tubing 1308 and the cannula 1307.

To remove the infusion flap 1301 from the cannula assembly 1302, one lifts up on, and rotates the infusion flap 1301 90 degrees so that the septum housing 1304 is once again perpendicular to the longitudinal axis of the cannula assembly 1302. The infusion flap 1301 is then disengaged by pinching the locking tangs 1401 and 1402 towards each other, and pulling the infusion flap 1301 away from the cannula assembly 1302.

In accordance with another embodiment of the invention, Fig. 19 is a cross-sectional view of an infusion flap 1901 attached to a cannula assembly 1902 that, similar to the above described embodiment, includes a single septum 1903 located in a rotatable septum housing 1904, but which has an alternative locking mechanism. Fig. 19 shows the infusion flap 1901 and the cannula assembly 1902 in a mated position, just prior to being latched. The insertion needle has been removed 1905.

The open ended female connector 1910 (see Fig. 20) on the infusion flap 1901, which seats the infusion needle 1909, is generally cylindrical shaped, such that the connector can be slid onto and mated with the male septum housing 1904. Figs. 20, 21, and 22 show a perspective view, a top view and a side view, respectively, of the infusion flap 1901 in position for mating with the cannula assembly 1902. The male septum housing 1904 includes a locking lug 2001 which mates with a lug receptacle 2002 on the connector 1910. The user aligns recepticle slot 2003 on the female connector 1910 with the locking lug 2001, such that the female connector 1910 can be slid onto, and mated with, the male septum housing 1904. Figs. 23 and 24 show a perspective view and a side view, respectively, of the infusion flap 1901 mated with the cannula assembly 1902. At this point, the infusion needle 1909 pierces the septum 1903 (see Fig. 19).

The locking lug 2001 is then engaged with the lug receptacle 2002 by rotating the infusion flap 25 counterclockwise (or clockwise depending on the location of the lug recepticle), as shown in Fig. 25. After engagement, the infusion flap 1901 and septum housing 1904 can be rotated 90 degrees, such that the infusion flap 1901 lays flat against the cannula assembly 1902, as shown in Fig. 26. A detent (not shown) may latch the infusion flap 1901 to the cannula assembly 1902 with a snap action. The flexible tube 1906 bends as the septum housing 1904 rotates, providing a leak tight fluid path between the tubing 1908 and the cannula 1907.

To remove the infusion flap 1901 from the cannula assembly 1902, one lifts up on a lift tab 2601 on the infusion flap 1901 and rotates the infusion flap 1901 90 degrees so that the septum housing 1904 is perpendicular to the longitudinal axis of the cannula assembly 1902. The infusion flap 1901 is then disengaged by rotating the infusion flap 90 degrees clockwise, and pulling the infusion flap 1901 away from the cannula assembly 1902.

Referring back to Fig. 1, the tubing 13 attaches at one end to a hub 12 for interfacing and receiving a fluid from a fluid delivery device (not shown). The fluid may be a drug, such as insulin. The fluid delivery device may be, without limitation, an infusion pump assembly.

The hub 12 may be of various shape. For example, the hub 12 may be asymmetric, circular, or elliptical in shape. The hub 12 may be made of plastic, metal, or other suitable material. The hub 12 may include a receptacle for receiving the tubing 13. The tubing 13 may be permanently attached to the hub 12 using a suitable adhesive. In other embodiments, the tubing 13 may be removably attached to the hub 12 using, for example, a luer connection.

The hub 12 may include a controller which allows the fluid delivery device to transition from a first configuration to a second configuration. The first and second configuration may be, for example, a pump reservoir load position and a pump operate position, respectively. While the controller is implemented as a flange in following Figs. 27-37, it is to be understood that the controller can be implemented in a wide variety of forms, such as, but not limited to, mechanical, electrical, magnetic, or optical forms. For example, without limitation, the hub 12 may include a flange or other mechanical protrusion that interfaces with the pump assembly, or the hub 12 may generate a magnetic field or optical signal that is sensed by a Hull Effect sensor or optical sensor positioned on the pump assembly, respectively. In still another embodiment, a wire in the hub 12 may complete a circuit in the pump assembly.

Fig. 27 is an overall view of a hub and infusion pump according to one embodiment of the present invention. A pump assembly 2710 contains the components needed to cause a reservoir assembly 2715 to deliver medication to a user. The reservoir assembly 2715 may contain enough medication, such as insulin, for several days for a typical user. A hub 2725 has a coupling to the reservoir assembly, the hub 2725 permanently affixed to a tubing set 2720 for delivery of the fluid to a patient.

Fig. 28 shows an exploded view of the drive mechanism of the infusion pump. The reservoir assembly 2715 comprises a reservoir 2830, plunger 2835 and plunger rod 2840. The reservoir 2830 contains the medication for delivery to the user and is of variable interior volume. The interior volume is the liquid capacity of the reservoir. The plunger 2835, inserted into the bottom of the reservoir, causes the volume of the reservoir to change as the plunger is displaced along the longitudinal axis of the reservoir. The plunger rod 2840 is connected to the plunger with the rod's longitudinal axis displaced from and parallel to the longitudinal axis of the reservoir. The plunger rod 2840 is threaded for at least a portion of the rod's length. A cylindrical pump barrel 2845 receives the reservoir assembly 2715. The pump barrel constrains the plunger rod, orienting the rod along the longitudinal axis of the barrel. The pump barrel 2845 is contained in the pump assembly and may contain a locking mechanism, such as a locking tab, to prevent rotation of the pump barrel with respect to the assembly. A gear box 2855 in the pump assembly 2715 includes a drive screw 2850 along with motor and gears to turn the drive screw. The drive screw 2850 is threaded and the screw's longitudinal axis is aligned parallel to and displaced from the longitudinal axis of the pump barrel. The hub 2725 has a coupling to the top of the reservoir.

Fig. 29 shows a pump barrel locking mechanism for an embodiment of the invention. The pump barrel 2845 includes a clearance hole 3072 in one end (shown in fig. 31) that guides the plunger rod 2840 during insertion of the reservoir assembly 2715 into the barrel 2845. To ensure that the drive screw 2850 does not interfere with the plunger rod 2840 during insertion of the reservoir assembly, the pump barrel 2845 maintains a fixed position relative to the pump assembly 2710. The position of the pump barrel relative to the pump assembly may be maintained, for example, by a locking tab 3060 included in the pump barrel that engages a pump barrel stop 3065 in the pump assembly 10. Fig. 30 is a detailed view of the pump barrel showing the locking tab 3060 and pump barrel stop 3066. Referring back to Fig. 29, the hub 2725 includes a flange 2970 which dislodges the locking tab 3060 from the barrel stop 3065 when the hub 2725 turns, allowing the hub 2725 to rotate the pump barrel 2845.

Figs. 31 and 32 are views along the longitudinal axis of the pump barrel 2845 showing the relation of the drive screw 2850 to the plunger rod 2840 in a loading position and in an engaged position, respectively. The reservoir assembly 2715 is positioned for loading so that the plunger rod 2840 does not contact the drive screw 2850, as shown in fig. 31. With the pump barrel 2845 positioned appropriately with respect to the pump

assembly 2710, the plunger rod 2840 clearance from the drive screw 2850 is determined by the placement of the clearance hole 3072 in the pump barrel 2845 base, which hole 3072 receives and guides the plunger rod 2840. The clearance hole 3072 may be tapered to ease insertion of the rod 2840. The drive screw 2850 fits in the clearance hole 3072 in the pump barrel 2845. Once the reservoir assembly 2715 is inserted into the pump assembly 2710, the barrel 2845 is rotated by the locking hub 2725, causing the plunger rod 2840 to turn and to engage the drive screw 2850, as shown in fig. 32. This embodiment advantageously simplifies reservoir loading.

In a specific embodiment of the invention, the plunger rod threads and the drive screw threads are buttress threads. This embodiment advantageously addresses eliminating reaction forces on the plunger rod normal to the direction of the rod's longitudinal axis. Such reaction forces may cause the rod to deflect and skip a thread on the drive screw, resulting in under delivery of medication to the user. Buttress threads eliminate the normal component of the reaction force.

In an embodiment of the present invention, the locking hub 2725 may be connected to the reservoir 2830 by a tapered luer connection, as shown in fig. 33. The reservoir has a male luer taper 3375 integrally molded into the reservoir's top. Surrounding the male luer is an annulus 3378 with an internal female thread. Similarly, the hub 2725 includes the mating female luer and threaded male connection.

In another embodiment of the invention, a needle connection is provided between reservoir 2830 and hub 2725. As shown in fig. 34, the reservoir includes a rubber septum 3480 that is attached to the reservoir with a crimped metal collar. A needle 3485, integral to the hub, pierces the septum and fluid can then flow from the reservoir to the tubing set.

In a further embodiment of the invention, as shown in fig. 35, an adapter 3595 is provided to permit a reservoir 3590 whose diameter is substantially smaller than the diameter of the pump barrel 2845 to be used with the pump assembly 2710. The adapter 3590 may be a separate component or may be integrated into the locking hub 2725. The adapter 3595 aligns and offsets the reservoir's 3590 axis parallel to the longitudinal axis of the pump barrel so that the plunger rod 2840, when rotated, mates with the drive screw. Figs. 36 and 37 shows an on-axis view of the small diameter reservoir 3590 when placed in the adapter 3595 in a loading position and in an engaged position, respectively. As will be apparent, the offset provided by the adapter allows the plunger rod 3840, when mated with the plunger 3835 and reservoir 3590, to engage the drive screw 3850 in the same fashion as for the embodiment shown in Figs. 31 and 32.

Having described various illustrative embodiments of the present invention, some of its advantages and optional features, it will be apparent that such embodiments are presented by way of example only and not by way of limitation. Those skilled in the art could readily devise alterations and improvements on these embodiments, as well as additional embodiments, without departing from the spirit and scope of the invention. All such modifications are within the scope of the invention as claimed.

What is claimed is:

1. A medical device for delivery of a fluid to a patient from a line terminating in a tubing needle, the medical device comprising:

a cannula assembly for coupling the fluid into a cannula for insertion into the patient, the cannula assembly having a first locking element disposed in a fixed position with respect to the cannula; and

an infusion flap for coupling the line to the cannula assembly, the infusion flap comprising:

a second locking element for engaging the first locking element of the cannula assembly; and

a lift tab for disconnecting the infusion flap from the cannula assembly, wherein coupling of the first and second locking elements requires initial mating of the infusion flap and cannula assembly followed by locking through rotation of the infusion flap with respect to the cannula assembly.

2. The medical device according to claim 1, where the first locking element is a locking lug and the second locking element is a lug receptacle.

3. The medical device according to claim 1, wherein the first locking element is a lug receptacle and the second locking element is a locking lug.

4. The medical device according to claim 1, wherein the cannula assembly includes a septum housing defining a core coupled to the cannula, the septum housing including a first septum positioned within the core at a first position, such that when the infusion flap and the cannula assembly are locked, the tubing needle penetrates the first septum so as to permit fluid communication between the line and the cannula.

5. The medical device according to claim 4, wherein the septum housing includes a second septum positioned within the core at a second position, such that an insertion needle can be introduced through the second septum into the cannula.

6. The medical device according to claim 1, wherein the cannula assembly includes a soft overmolded body.

7. A medical device according to claim 1, the cannula assembly further including:

a flexible tube in fluid communication with the cannula; and

a septum in fluid communication with flexible tube, wherein, when the flexible tube is in a first position, an insertion needle can be introduced through the septum into the cannula, and when the flexible tube is in a second position, a tubing needle inserted through the septum permits fluid communication between the line and the cannula.

8. The device according to claim 1, further comprising an insertion flap, the insertion flap including an insertion needle for inserting into the passagway through the septum, the insertion flap when inserted further extending through the cannula and terminating with a sharp distal end disposed slightly beyond a distal end of the cannula.

9. The device according to claim 1, wherein the insertion flap has an interface for coupling to an auto-insertion device.

10. A medical device for delivery of a fluid to a patient from a line terminating in a tubing needle, the medical device comprising:

a cannula for insertion into the patient;

a flexible tube in fluid communication with the cannula; and

a septum in fluid communication with the flexible tube, wherein when the flexible tube is in a first position, an insertion needle can be introduced through the septum into the cannula, and when the flexible tube is in a second position , a tubing needle inserted through the septum permits fluid communication between the line and the cannula.

11. The device according to claim 10, further comprising:

an infusion flap that includes the tubing needle; and

a cannula assembly that includes the cannula;

wherein when the infusion flap and cannula assembly are mated, the tubing needle passes through the septum permitting fluid communication between the line and the cannula.

12. The device according to claim 11, further comprising a locking mechanism for securing the infusion flap to the cannula assembly.

13. The device according to claim 12, wherein the locking mechanism includes a locking tang on the infusion flap, the locking tang inserted into a tang receptacle on the cannula assembly.

14. The medical device according to claim 12, wherein the septum is disposed in a septum housing, and the locking mechanism includes a first locking element disposed on the septum housing and a second locking element disposed on the infusion flap, wherein coupling of the first and second locking elements requires initial mating of the infusion flap and cannula assembly followed by locking through rotation of the infusion flap with respect to the cannula assembly.

15. The medical device according to claim 14, where the first locking element is a locking lug and the second locking element is a lug receptacle.

16. The medical device according to claim 14, wherein the first locking element is a lug receptacle and the second locking element is a locking lug.

17. The device according to claim 14, wherein the septum housing can be rotated to a mating position that allows the infusion flap and the septum housing to be mated together and the infusion flap rotated with respect to the cannula assembly to lock the infusion flap onto the septum housing, and

wherein the septum housing can then be rotated to a stable position that prevents rotation of the infusion flap.

18. The device according to claim 10, further comprising an insertion flap, the insertion flap including an insertion needle for inserting into the passagway through the septum, the insertion flap when inserted further extending through the cannula and terminating with a sharp distal end disposed slightly beyond a distal end of the cannula.

19. The device according to claim 18, wherein the insertion flap has an interface for coupling to an auto-insertion device.

20. A method for delivering a fluid to a patient from a line terminating in a tubing needle, the method comprising,

inserting an insertion needle through a septum and a cannula, the septum and the cannula having a relative orientation;

inserting the cannula into tissue of a patient;

withdrawing the insertion needle from the cannula and the septum;

inserting the tubing needle through the septum;

varying the relative orientation between the septum and the cannula; and

delivering a fluid through the line and the cannula.

21. A tubing set for coupling a fluid delivery device into fluid communication with a cannula assembly, the fluid delivery device having a first configuration and a second configuration, the tubing set comprising:

a length of tubing having a first end and a second end;

a hub coupled to the first end for connecting to the fluid delivery device, the hub including a controller for allowing fluid delivery device to transition from the first configuration to the second configuration; and

an infusion flap coupled to the second end for connecting to the cannula assembly.

22. The tubing set according to claim 21, wherein the first configuration of the source is a reservoir load position and the second configuration is an operate position.

23. The tubing set according to claim 21, wherein the controller is capable of allowing the fluid delivery device to transition from the second configuration to the first configuration.

24. The tubing set according to claim 21, wherein the controller includes a flange that interfaces with the fluid delivery device.

25. The tubing set according to claim 21, wherein the controller includes generating one of an optical signal and magnetic field.

26. The tubing set according to claim 21, wherein the controller includes an electronic circuit to the fluid delivery device.

27. The tubing set according to claim 21, wherein the hub includes a luer connector for mating with the fluid delivery device.

28. The tubing set according to claim 21, wherein the fluid delivery device is an infusion pump having a reservoir with variable volume and a drive assembly, the drive assembly including a barrel having a clearance hole in a barrel end, the barrel characterized by a longitudinal barrel axis of rotation, the drive assembly further including a plunger rod inserted through the clearance hole, and a rotating drive screw with external threads that removably engages with threads on the plunger rod by rotating the barrel about the barrel axis, the external threads engaged with the threads on the plunger rod when in the first configuration and the external threads disengaged with the threads on the plunger rod when in the second second configuration, and

wherein the controller is capable of allowing the barrel to rotate so as to bring the rod threads in and out of mechanical engagement with the drive screw threads.

29.The tubing set according to claim 28, wherein the controller includes a flange for dislodging a locking tab on the barrel, allowing the barrel to rotate.

30. The tubing set according to claim 20, wherein the cannula assembly has a first locking element disposed in a fixed position with respect to the cannula; and

the infusion flap includes:

a tubing needle;

a second locking element for engaging the first locking element of the cannula assembly; and

a lift tab for disconnecting the infusion flap from the cannula assembly, wherein coupling of the first and second locking elements requires initial mating of the infusion flap and cannula assembly followed by locking through rotation of the infusion flap with respect to the cannula assembly.

31. The tubing set according to claim 30, wherein the tubing needle penetrates a septum in the cannula assembly when the infusion flap is locked to the cannula assembly, permitting fluid communication between the tubing set and a cannula protruding from the cannula assembly.

32. A conduit for coupling to a fluid delivery device, the fluid delivery device having a first configuration and a second configuration, the conduit comprising:

a length of tubing having a first end; and

a hub coupled to the first end for connecting to the fluid delivery device, the hub including a controller for allowing the fluid delivery device to transition from the first configuration to the second configuration.

33. The conduit according to claim 32, wherein the first configuration is a reservoir load position and the second configuration is an operate position.

34. The conduit according to claim 32, wherein the hub includes a luer connector for mating with the fluid delivery device.

35. The conduit according to claim 32, wherein the controller includes a flange that interfaces with the fluid delivery device.

36. The conduit according to claim 32, wherein the controller includes generating one of an optical signal and magnetic field.

37. The conduit according to 32, wherein the controller includes completing an electronic circuit in the fluid delivery device.

38. A method of providing flow of a fluid from a fluid delivery device to a porous medium, the method comprising:

coupling a hub to the fluid delivery device, the hub permanently affixed to a tube set;

controlling a configuration of the fluid delivery device via the hub; and

coupling the tube set to the porous medium so as to allow fluid to flow from the fluid delivery device to the porous medium.

39. The method according to claim 38, wherein controlling the configuration of the fluid delivery device includes allowing the pump to move from a first configuration to a second configuration.

40. The method according to claim 39, wherein the first configuration of the fluid delivery device is a load position and the second configuration is an operate position.

41. The method according to claim 38, wherein controlling the configuration of the fluid delivery device includes moving a flange on the hub.

42. The method according to claim 38, wherein controlling the configuration of the fluid delivery device includes generating one of a magnetic field and an optical signal.

43. The method according to claim 38, wherein the fluid delivery device is an infusion pump.

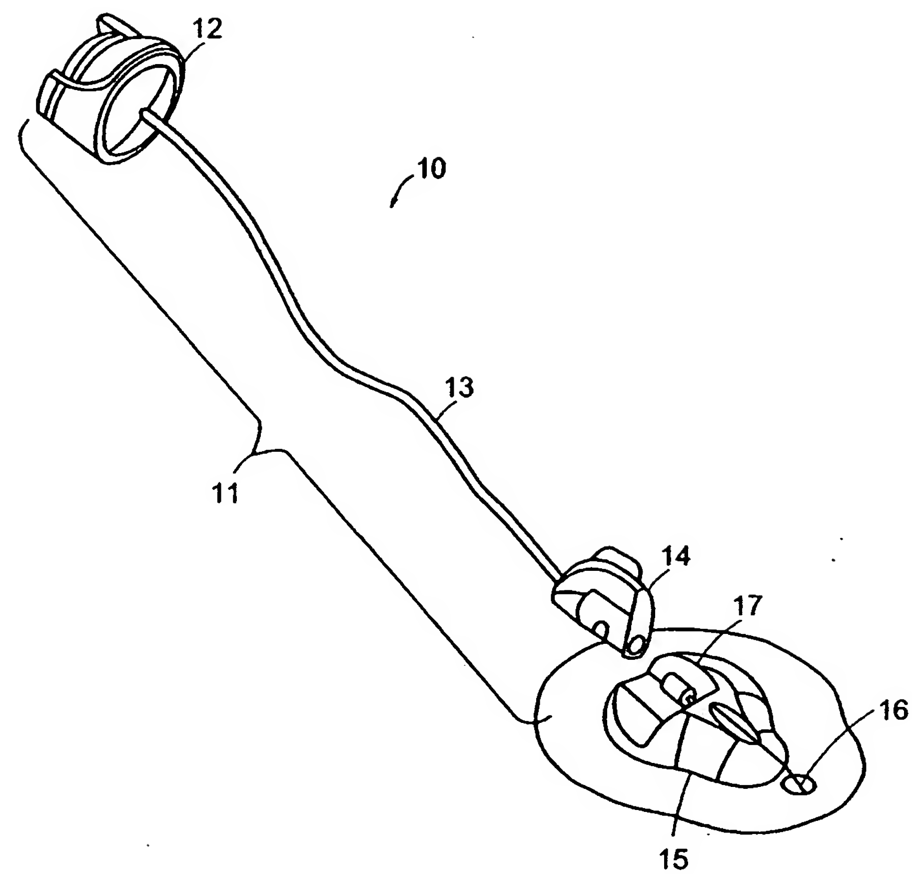

FIG. 1

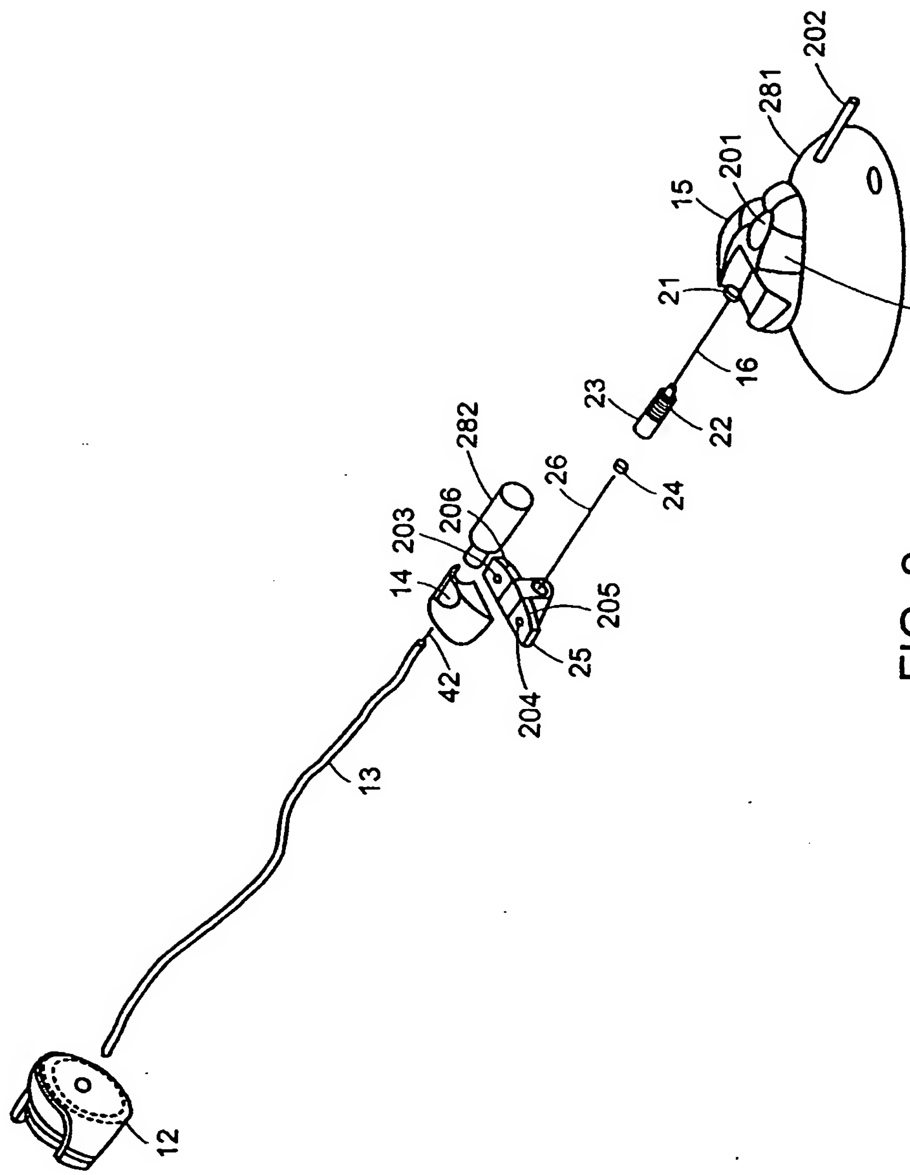
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FIG. 2

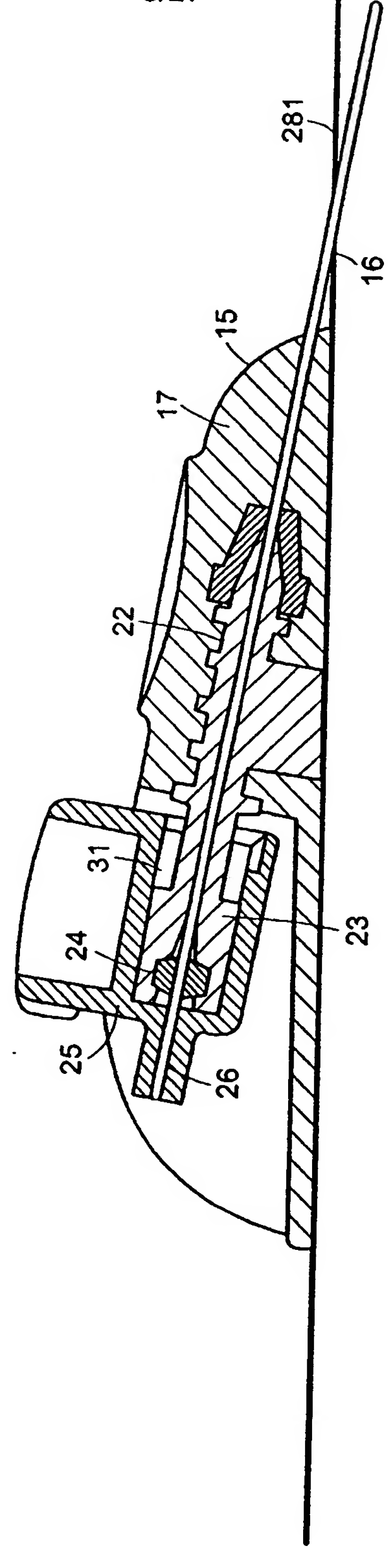

FIG. 3

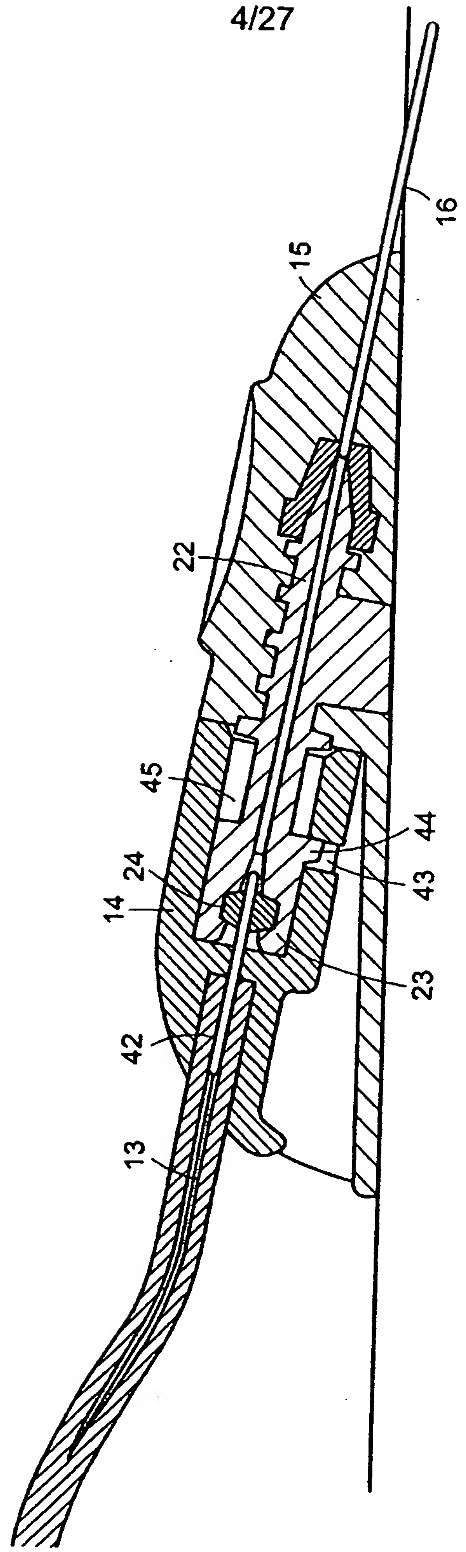

FIG. 4

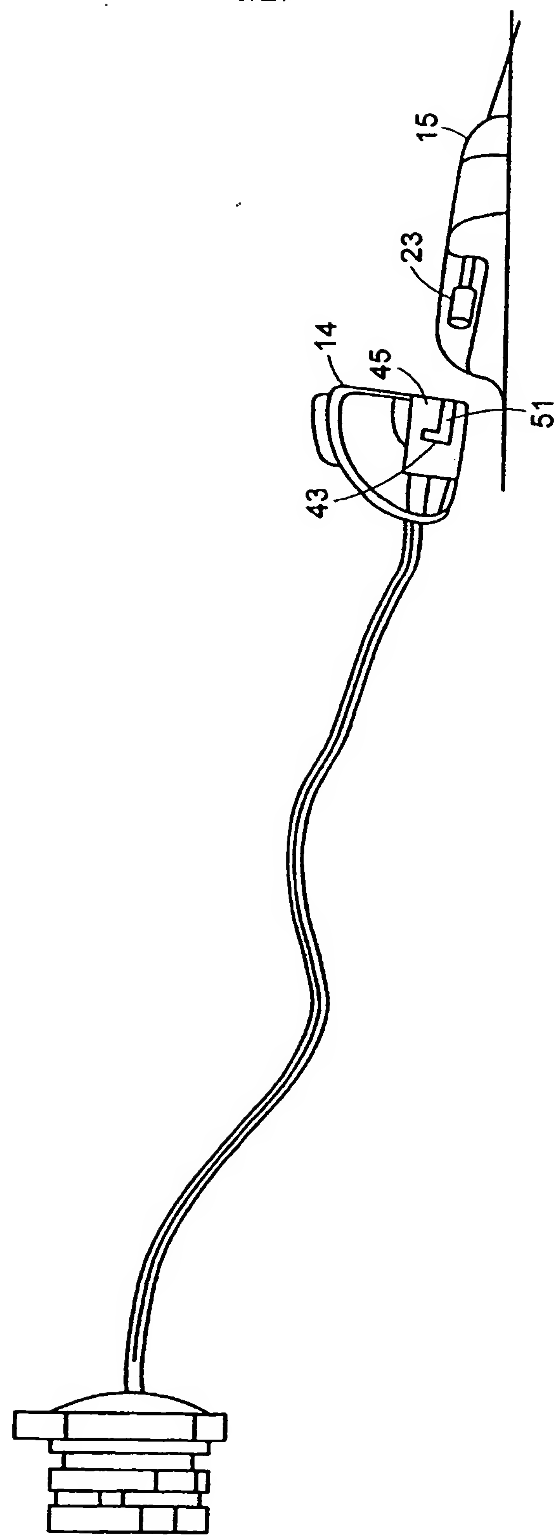

FIG. 5

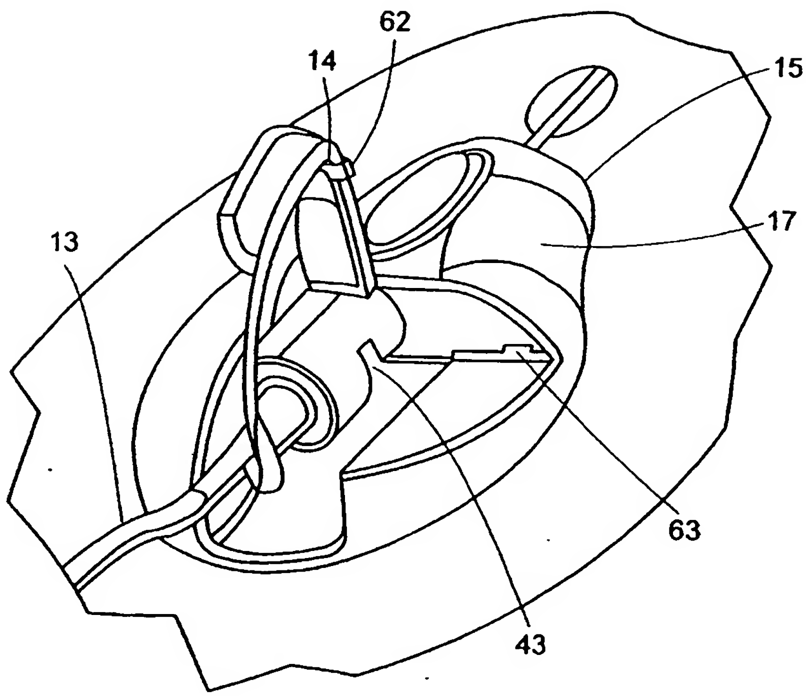

FIG. 6

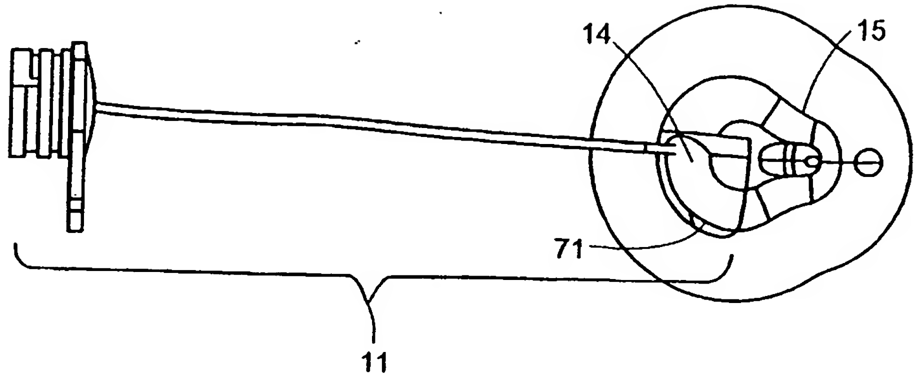

FIG. 7

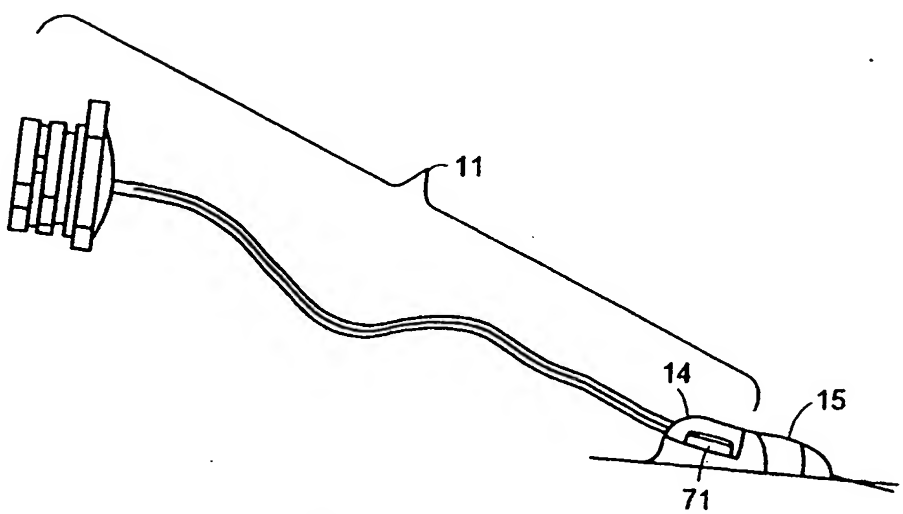

FIG. 8

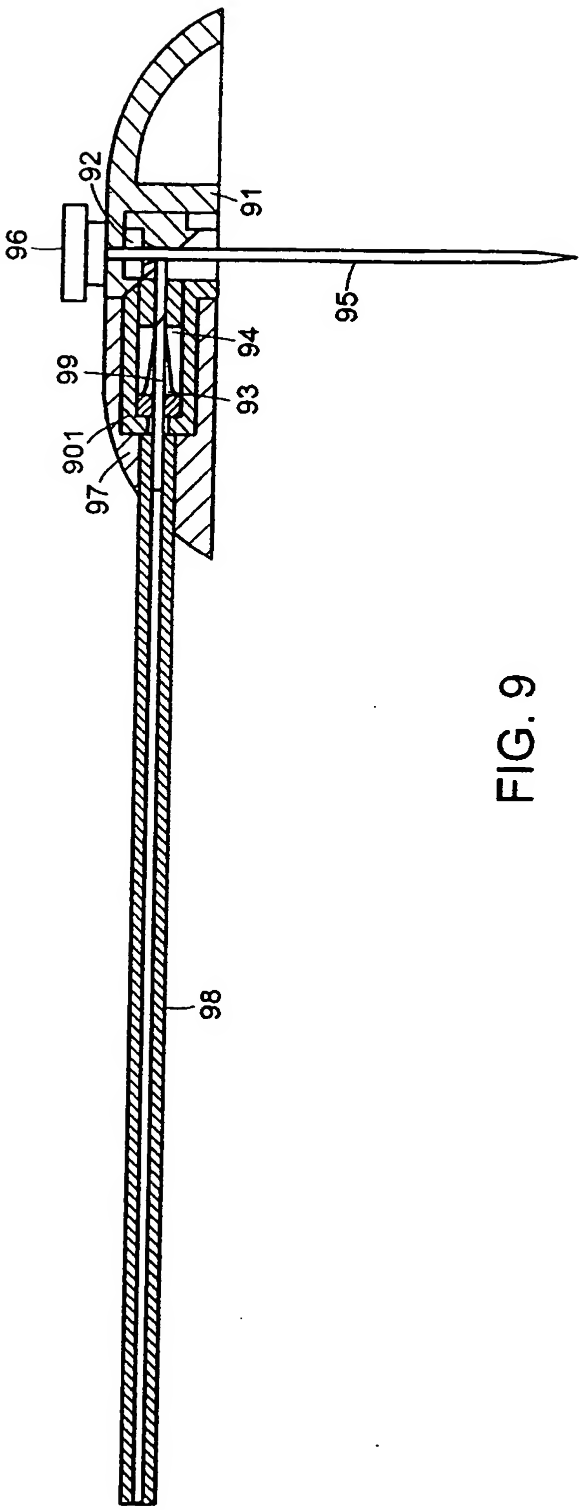

FIG. 9

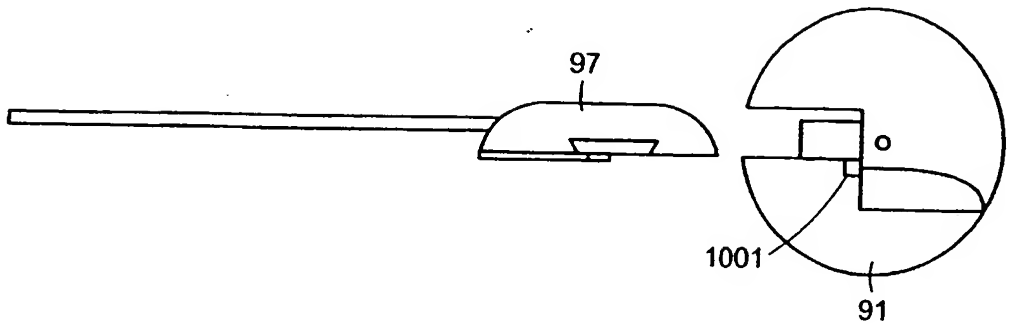

FIG. 10

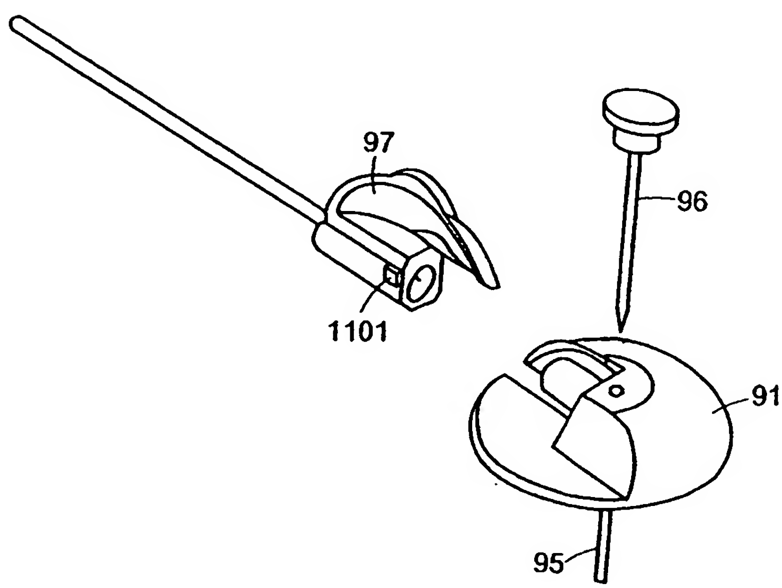

FIG. 11

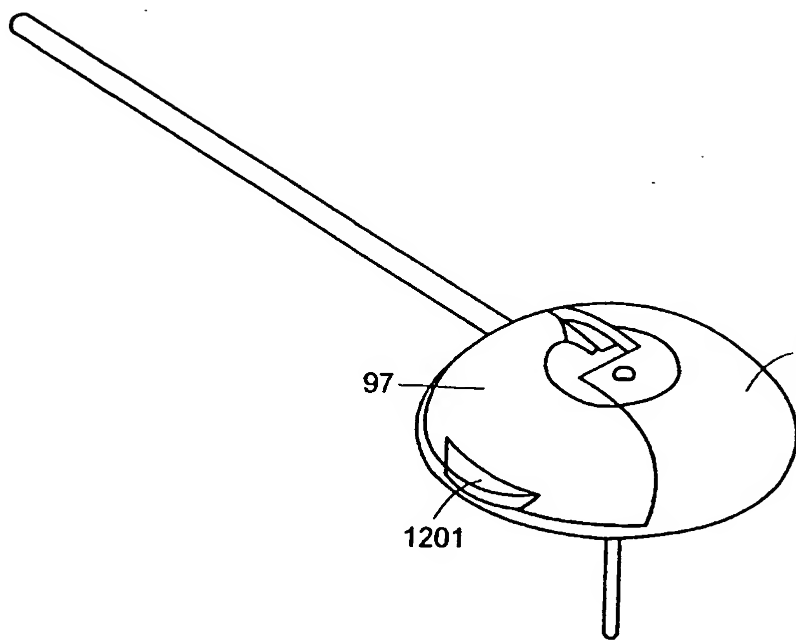

FIG. 12

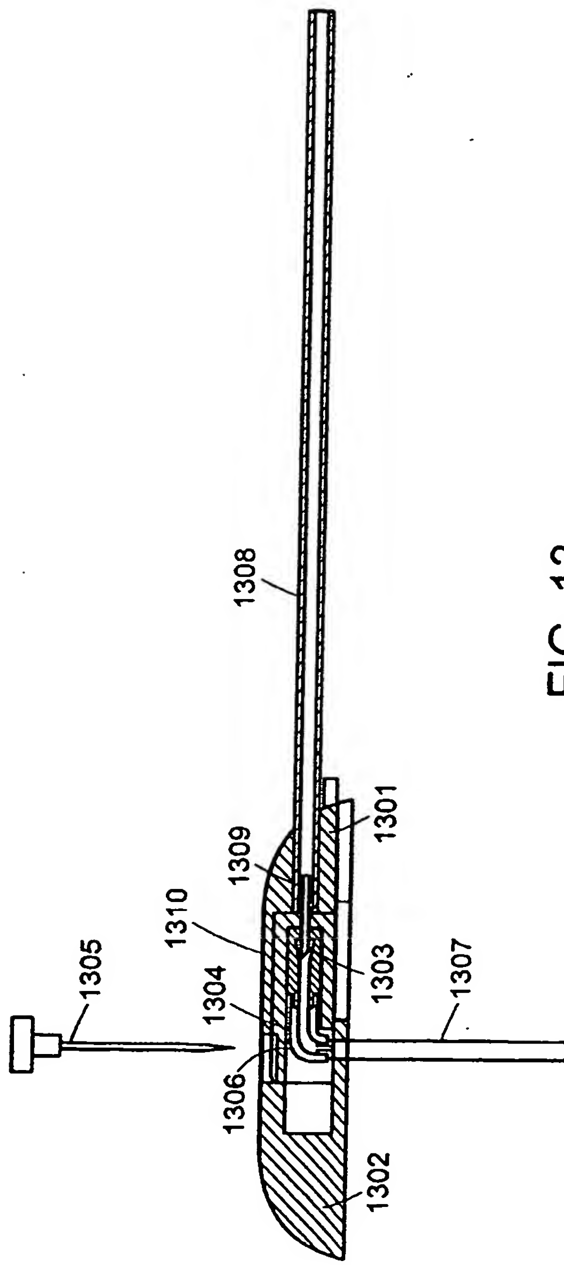

FIG. 13

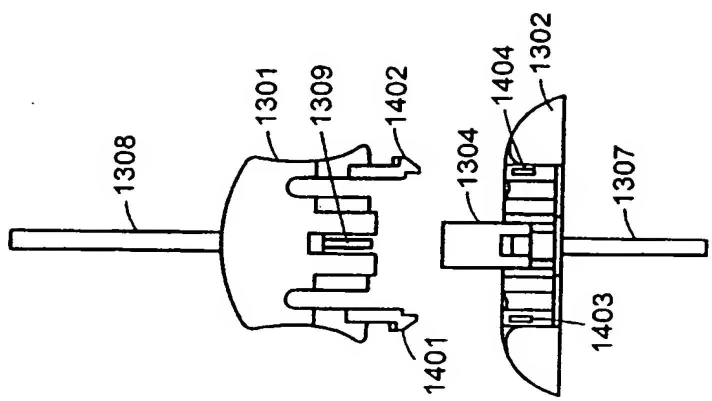
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FIG. 15

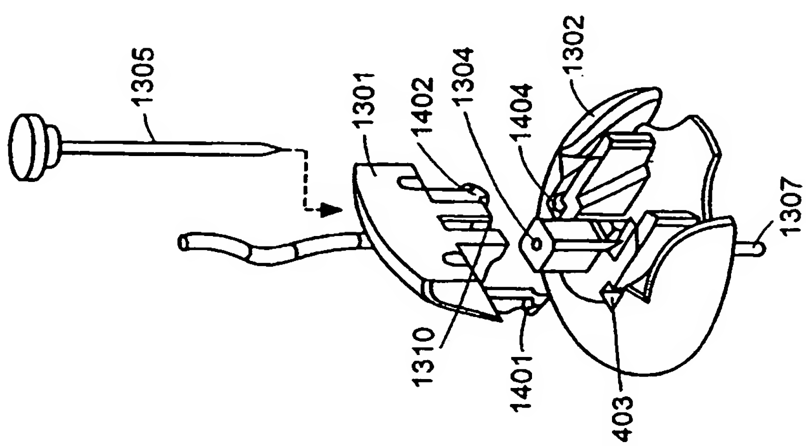
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FIG. 14

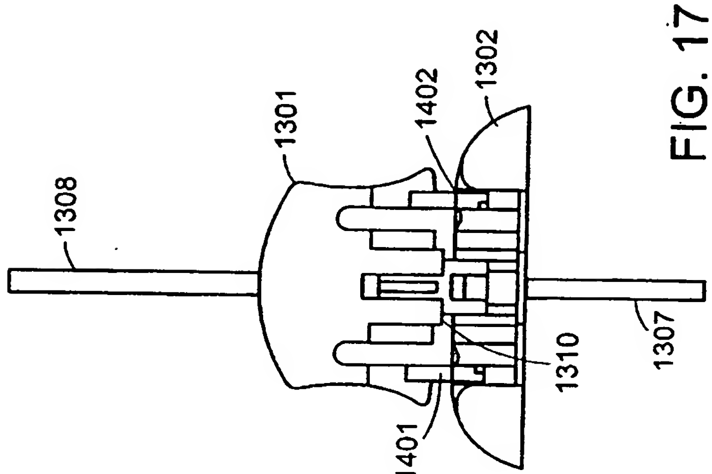

FIG. 17

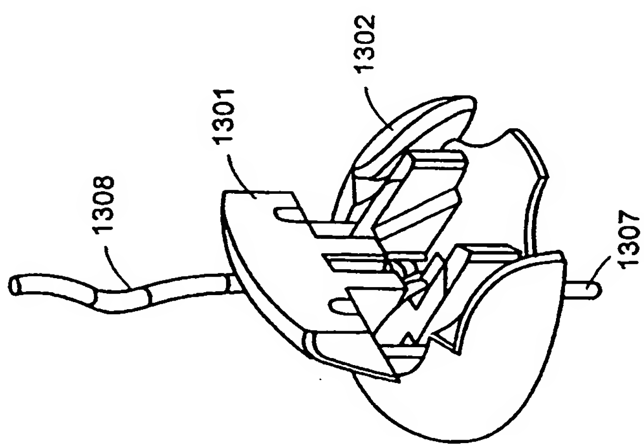

FIG. 16

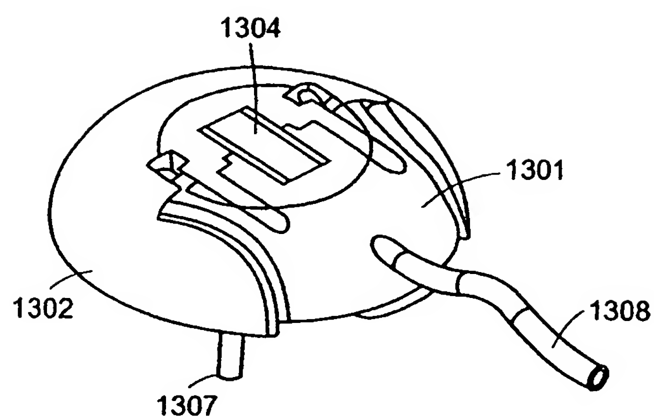

FIG. 18

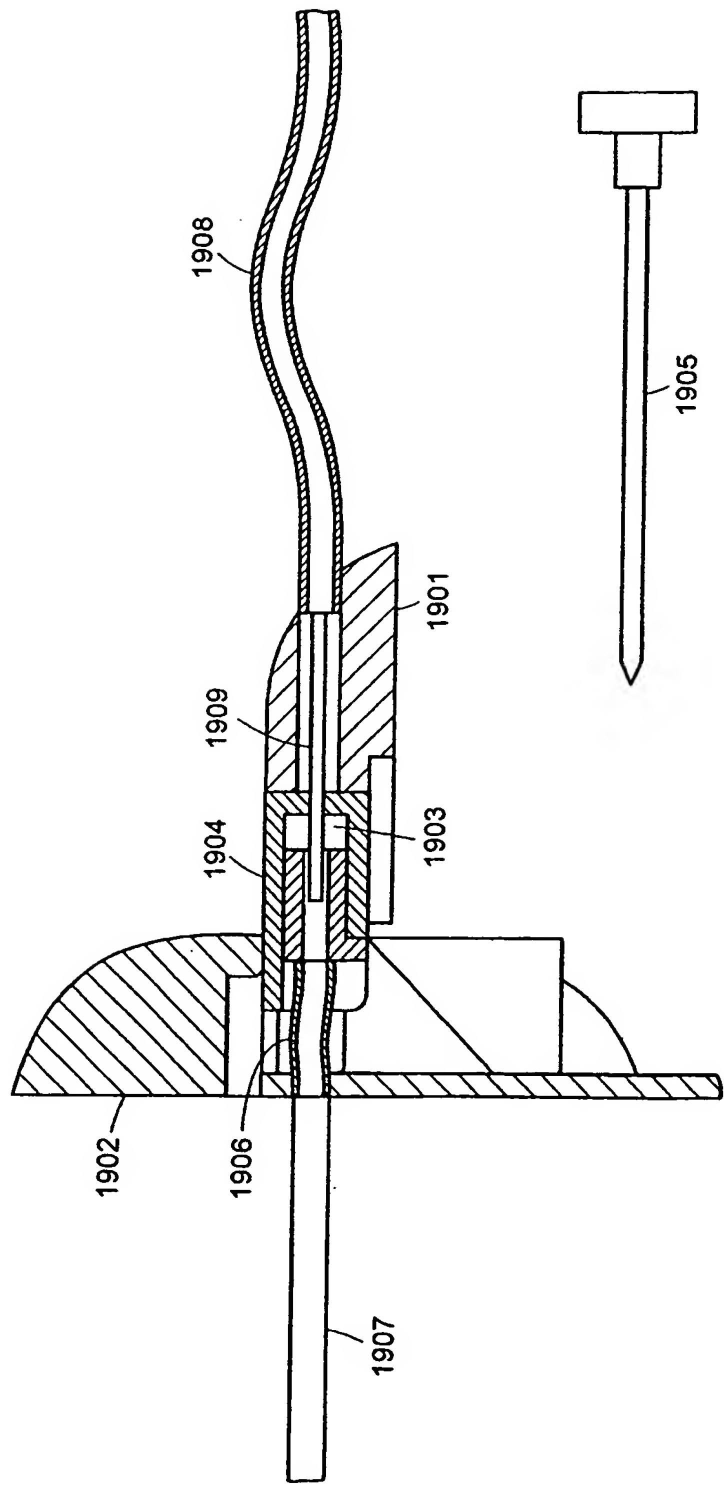

FIG. 19

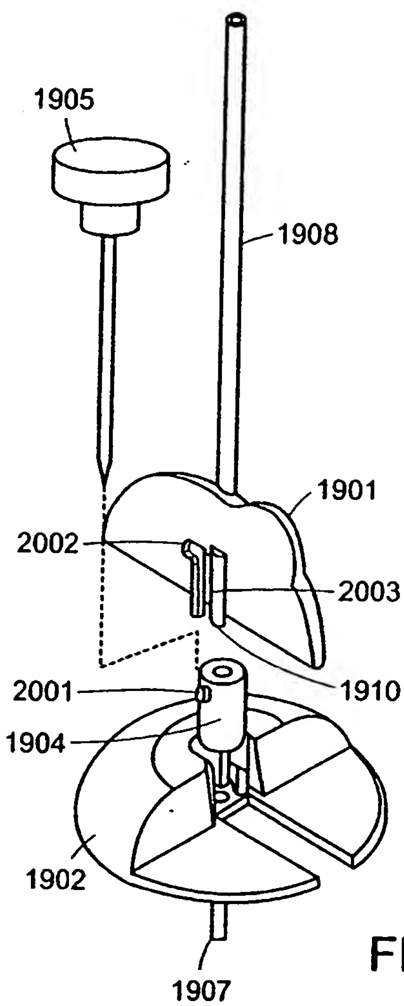

FIG. 20

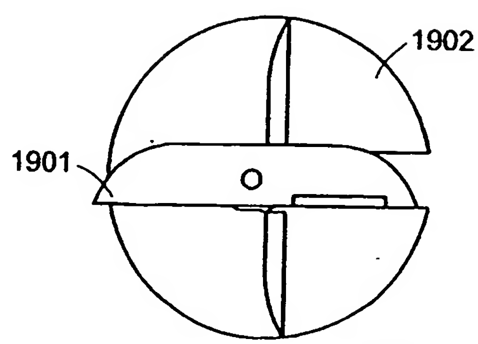

FIG. 21

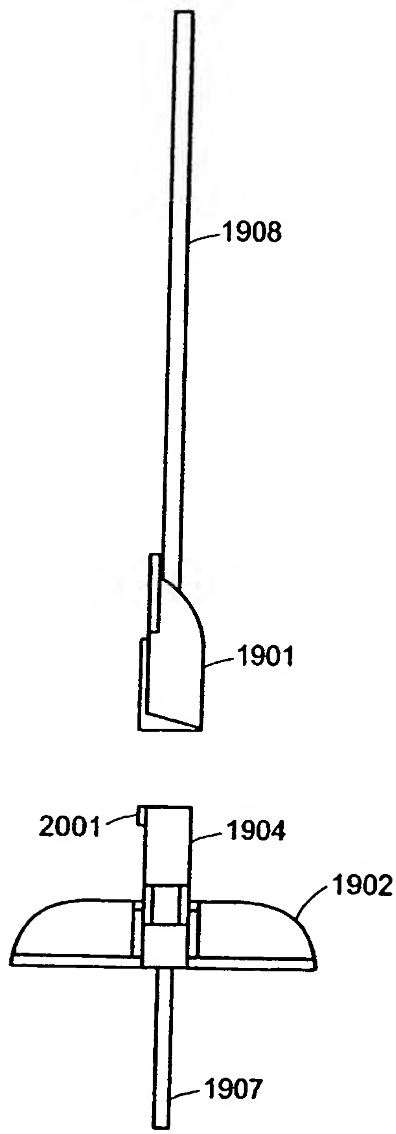

FIG. 22

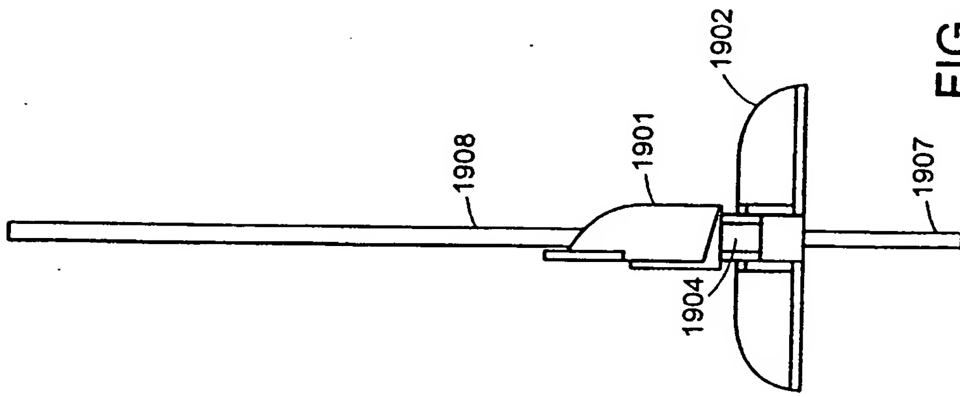

FIG. 24

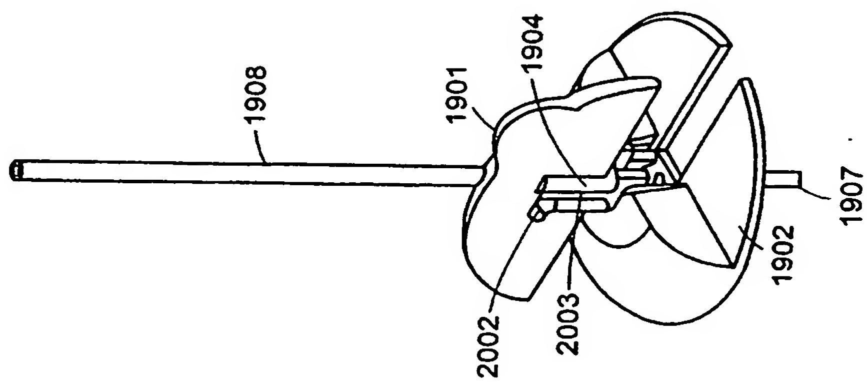

FIG. 23

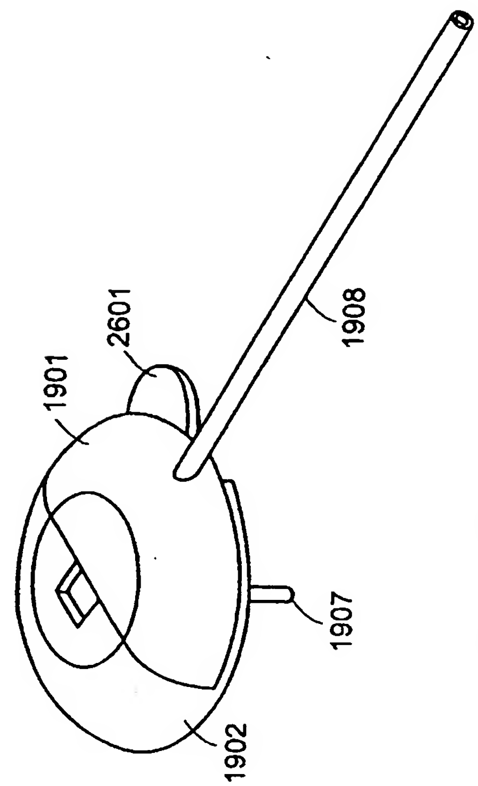

FIG. 26

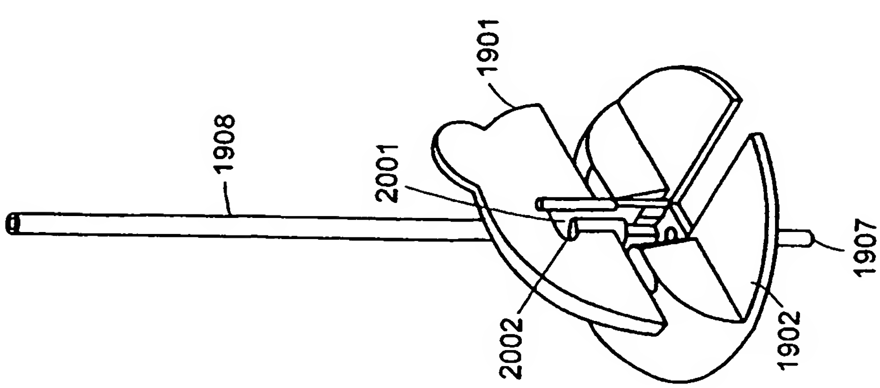

FIG. 25

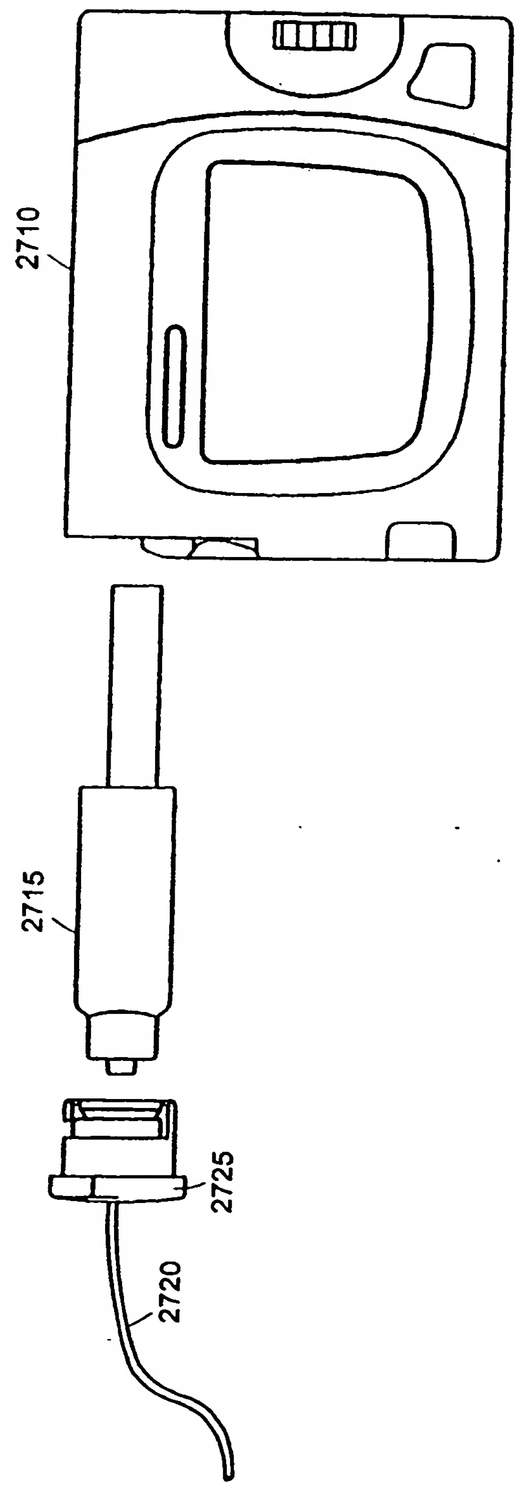

FIG. 27

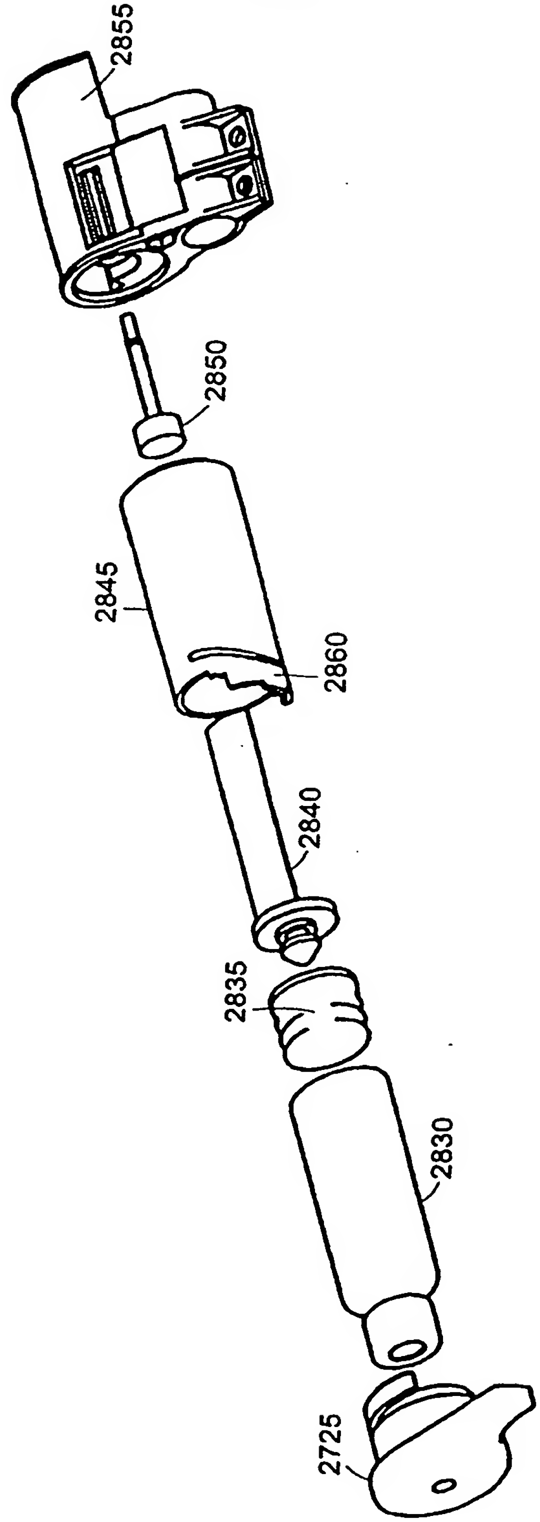

FIG. 28

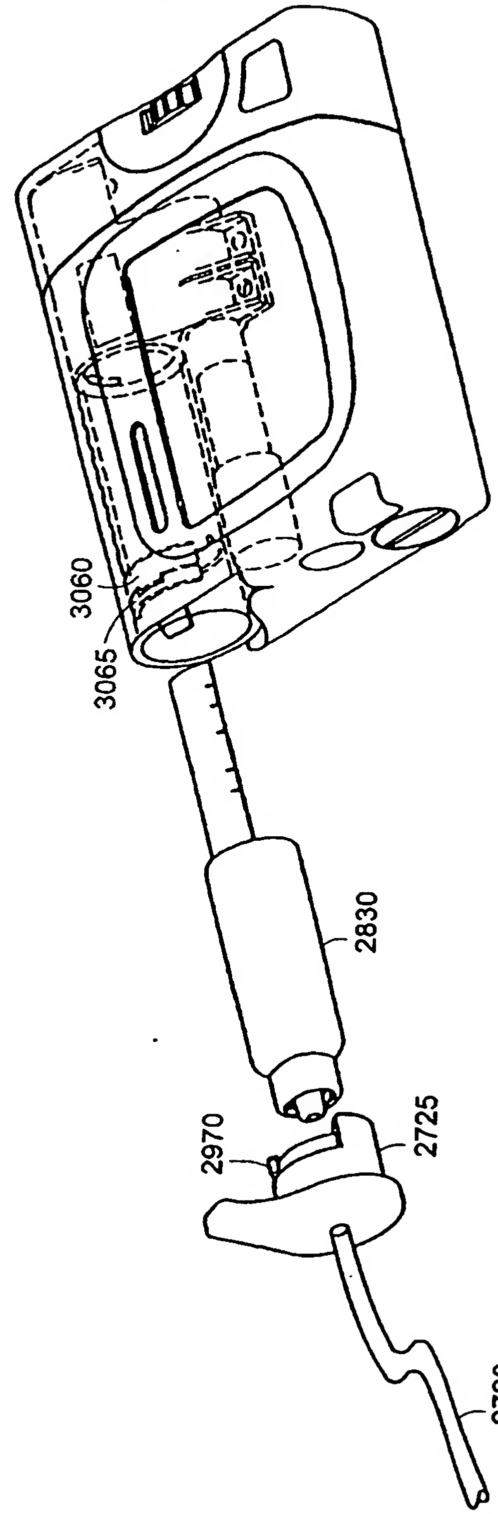

FIG. 29

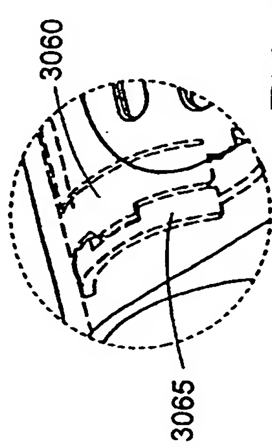

FIG. 30

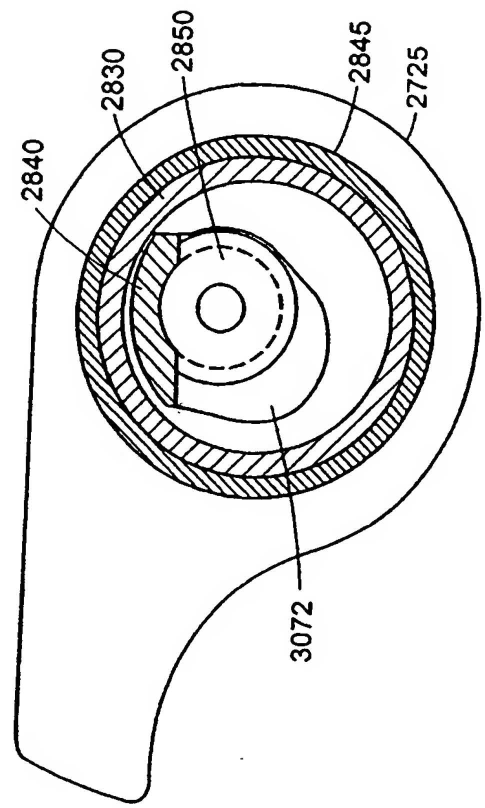

FIG. 32

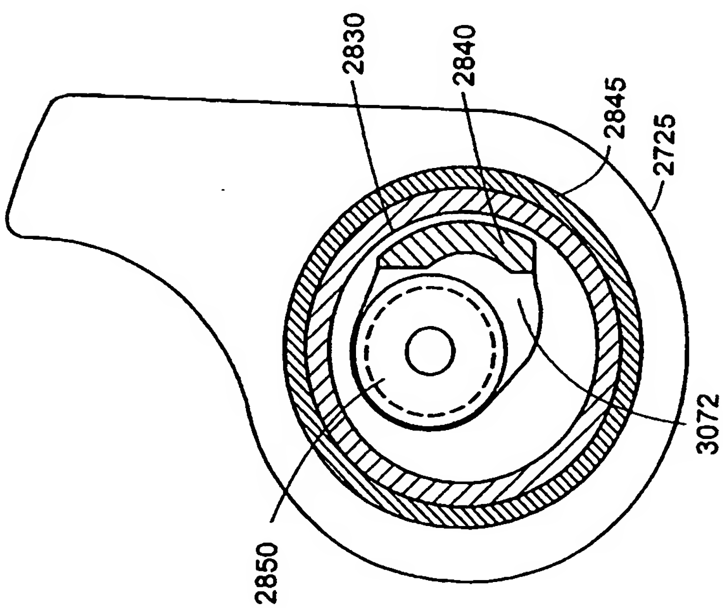

FIG. 31

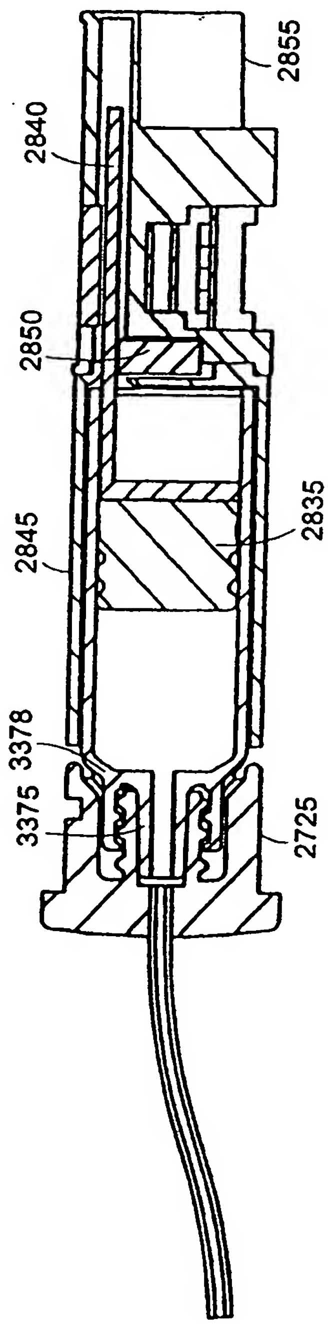

FIG. 33

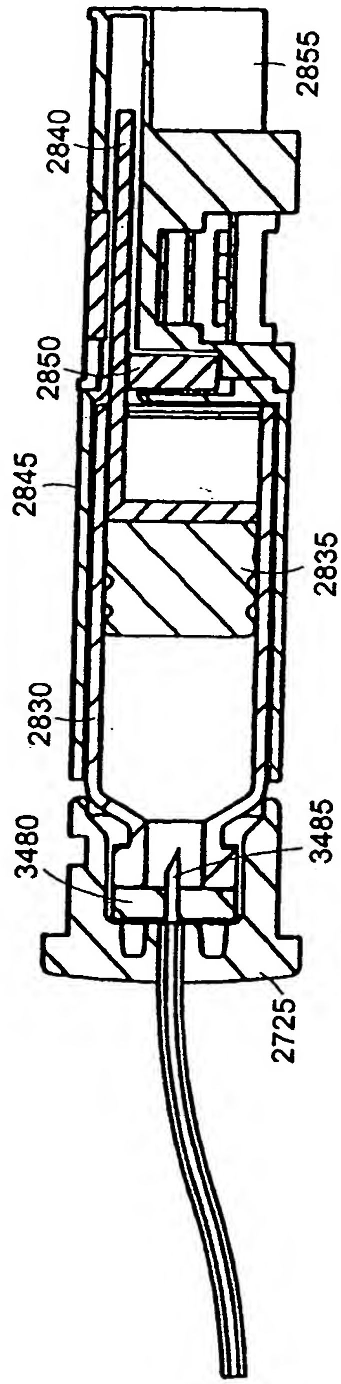

FIG. 34

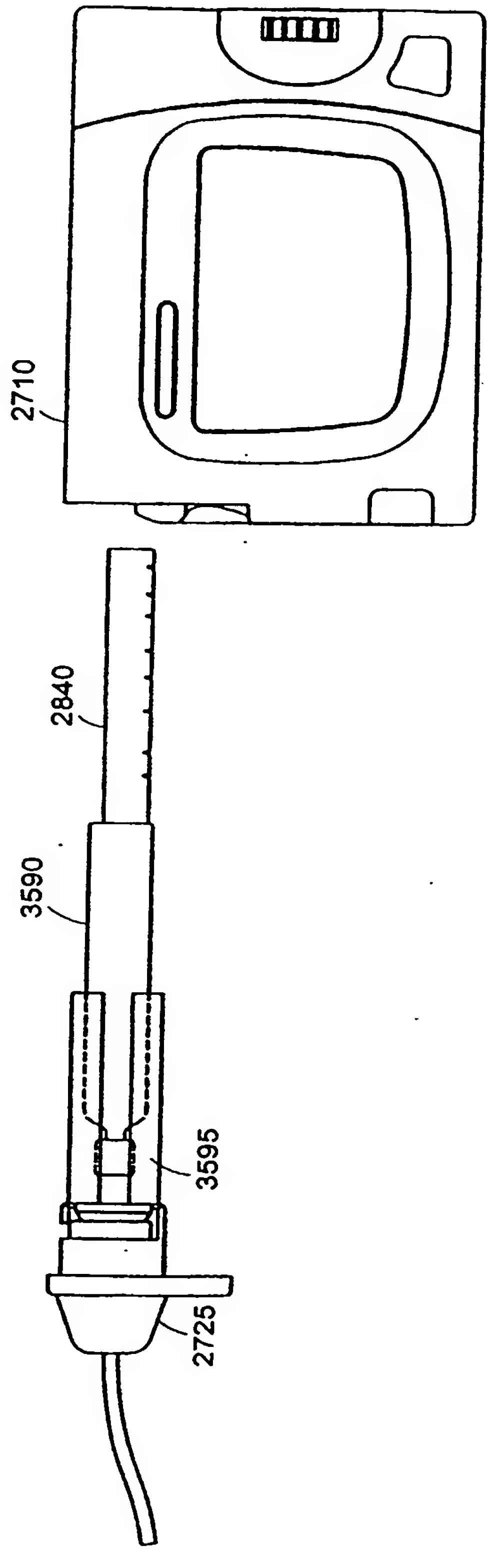

FIG. 35

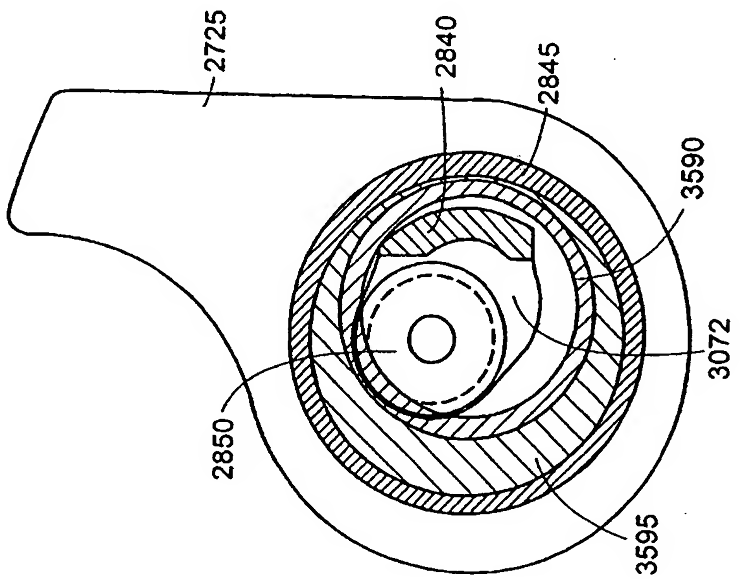
2725
2840
2845
3590
3072
2850
3595

FIG. 37

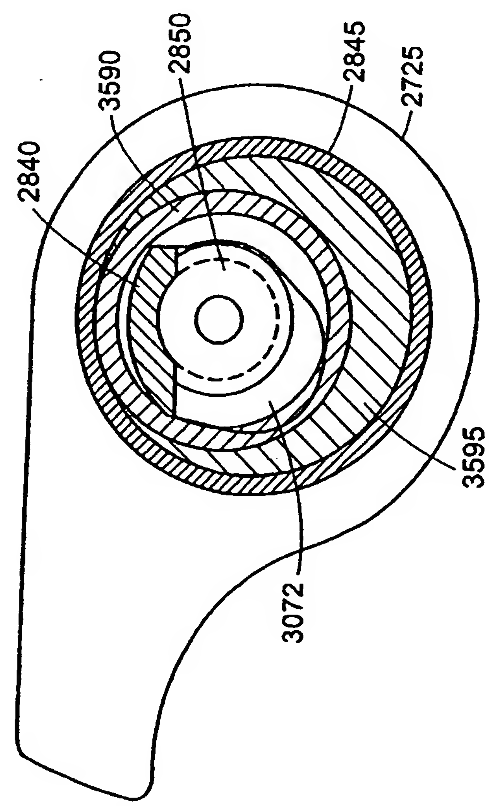
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FIG. 36